Geisinger

**POLICY NUMBER: 3.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Geisinger Health Plan (GHP) Formulary Exception**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee.

The Plan's Department of Pharmacy maintains a process by which a member or healthcare provider can request a formulary exception for specific drugs, drugs used for an off-label purpose, and biologicals and medications not included in the Health Plan's drug formulary. Members and healthcare providers can initiate requests for a formulary exception by contacting Pharmacy Services by phone, fax, or written request.

Formulary exception requests will be evaluated, and a determination of medical necessity made utilizing all the following criteria:

1. Member's eligibility to receive requested services (enrollment in the plan, prescription drug coverage, specific exclusions in member's contract).
2. Utilization of the requested agent for a clinically proven treatment indication or diagnosis.
3. Therapeutic failure, intolerance, or contraindication to use of formulary agents and/or agents designated as therapeutically equivalent.
4. Appropriateness of the nonformulary agent compared with available formulary agents (including but not limited to):
    A. Safety.
    B. Efficacy.
    C. Therapeutic advantage as demonstrated by head to head clinical trials.
    D. Meets Health Plan criteria for drug or drug class formulary exception.
5. Additional policies that may be referenced as part of a coverage decision include:
    A. Policy 9.0 Brand
    B. Policy 296.0 Triptan Quantity Limit Exceptions
    C. Policy 469.0 Statin Quantity Limit Exceptions
    D. Policy 487.0 Quantity Limit Exceptions

| Geisinger | POLICY NUMBER: 3.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Geisinger Health Plan (GHP) Formulary Exception** |

**PURPOSE/OBJECTIVE:**

The purpose of the Formulary Exception process is to provide a mechanism whereby an exception can be made for coverage of medications as noted above when a member or healthcare provider initiates such a request for coverage. Medications that are benefit exclusions are not eligible for review through the exception process.

This policy will be maintained in compliance with the standards of NCQA and any other applicable state and federal regulatory entities.

Member confidentiality will be maintained as outlined in the Health Plan Administrative Policy #02, Privacy and Confidentiality.

**RESPONSIBILITY**

Geisinger Health Plan Pharmacy Department
Geisinger Health Plan Medical Directors
Geisinger Health Plan Advisory Committee

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary ("Drug Formulary")*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***FDA*** – Food and Drug Administration.
3. ***Formulary (Drug Formulary) products*** – prescription medications that meet criteria for Formulary inclusion.
4. ***Nonformulary products*** – those medications which are not included in the Formulary.
5. ***Healthcare Provider*** - a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
6. ***Specialist*** – a healthcare provider whose practice is not limited to primary health care services and who has additional post-graduate or specialized training, has board

certification or practices in a licensed specialized area of health care and is actively practicing (i.e., Gynecology, Neurology).

7. ***NCQA*** – National Committee for Quality Assurance.
8. ***GHP*** – Geisinger Health Plan or "Plan."
9. ***New drugs (medications)*** – those medications that have been FDA-approved and available on the market for a period of six months or less.
10. ***P&T Committee*** – Pharmacy and Therapeutics Committee.
11. ***Urgent Care Claim*** – care for which a request to extend a course of treatment beyond the initially approved period of time or number of treatments must be decided, and notification made, within not more than 24 hours (provided that the claim is made at least 24 hours prior to the expiration of the initial approval period); or a claim for care that, if subjected to normal timeframes, could seriously jeopardize the life or health of the claimant (or his or her ability to regain maximum function), or subject the claimant to severe pain that cannot be managed adequately.
12. ***Pre-Service Claim*** – any claim for benefits that, under the terms of the plan, must be approved (either in whole or part) before medical care is obtained.
13. ***Post-Service Claim*** – any claim for benefits that is not a pre-service claim.
14. ***Adverse benefit determination*** – a denial, reduction, or termination of benefits or a failure to provide or pay for benefits.
15. ***Date received (received, receipt)*** – date and time received by Geisinger Health Plan, regardless of which department receives it.
16. ***PAHub –*** electronic solution that is used by Geisinger Health Plan to track, monitor, and complete all requests for pharmacy medication reviews. This includes an activity log capturing the dates and times of all actions completed for each request.
17. ***Written notification date*** – date and time the written notification leaves Geisinger Health Plan via mail or fax.
18. ***CPhT –*** Certified pharmacy technician
19. ***LPN –*** Licensed practical nurse

**PREREQUISITES**

Plan Members with a prescription drug rider, including all lines of business, unless a specific limitation or exception exists.

**PROCEDURE:**

1. A member or their healthcare provider may initiate a request for a formulary exception in accordance with the following:
    A. Requests should be directed to the Department of Pharmacy Services (as communicated in writing through the member handbook, provider guide, on-line pharmacy service, the formulary and written communication to members and providers).
    B. Information needed for an exception include, but is not limited to, the following:
        (1) Caller's name and telephone number;

(2) Member's medical record number and insurance identification number;
(3) Prescribing healthcare provider's name and telephone number;
(4) The exception requested;
(5) Clinical rationale including medical records, laboratory data, past treatment history and other documentation, as determined by the Plan to be relevant.

2. Requests for exception are reviewed and a determination of coverage made within a timeframe in accordance with the following:
   A. When the request for coverage is related to an Urgent Care Claim, a determination of coverage will be made within 24 hours of receipt of the necessary information.
   B. When the request for coverage is deemed to be a Pre-Service or Post-Service claim, a determination of coverage will be made within 48 hours of the receipt of the necessary information.
   C. All requests for GHP Kids members will be reviewed within 24 hours of receipt of the necessary information.
3. Requests for exception will be reviewed as follows:
   A. A Certified Pharmacy Technician (CPhT) or Licensed Practical Nurse (LPN), under the supervision of a Health Plan Pharmacist, will perform an initial review of medical record documentation and treatment history to recommend approval or denial of cases where there are explicit utilization management criteria and no clinical judgement is required.
      (1) If the request for exception is approved, no further action will be required on the part of the Health Plan Pharmacist or the Licensed Physician.
      (2) If the CPhT or LPN recommends denial upon initial review, the case will be forwarded to a Health Plan Pharmacist for review.
   B. For all cases where clinical judgement is required, explicit utilization management criteria do not exist, or those which a CPhT or LPN recommends denial, a Health Plan Pharmacist will perform an initial review of medical record documentation and treatment history to recommend approval or denial.
      (1) If the request for exception is approved, no further action will be required on the part of the Licensed Physician.
      (2) If the Health Plan Pharmacist recommends denial upon initial review, the case will be forwarded to a Licensed Physician for review.
   C. A Licensed Physician shall make the final decision in all instances where a Health Plan Pharmacist recommends denial based on medical necessity and appropriateness.

4. Based on the determination of coverage made, one of the following will occur:
    A. If the formulary exception is approved:
        (1) An electronic override will be entered into the pharmacy claims adjudication system.
            a. The Member (or Member's authorized representative) and Healthcare Provider will be verbally notified of the determination of coverage within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent.
            b. At the time of notification, the Plan will indicate the coverage provided in the amount disclosed by the Plan for the service requested.
        (2) A written confirmation of the approval will be sent to the provider and Member (or Member's authorized representative) within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent.
    B. If the request for a formulary exception is denied, resulting in an adverse benefit determination, the following will occur:
        (1) The Healthcare Provider and Member (or Member's authorized representative) will be verbally notified of the adverse determination within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent.
        (2) This verbal notification will include instructions on how to initiate a Grievance and/or Appeal Process. (For additional information on appeals see Policy 4.0.)
        (3) The prescribing healthcare provider will be offered the opportunity to discuss the determination of coverage with a Plan Pharmacist or a Plan Medical Director.
        (4) The Member (or Member's authorized representative) and Healthcare Provider will be sent a written confirmation of the adverse benefit determination within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent. The written notification shall include the specific reason for the determination, the basis and clinical rationale utilized in rendering the determination of coverage (if applicable), any internal policy or criterion applied (if applicable) as well as instructions regarding initiation of the Grievance and/or Appeal Process.
5. Documentation of the determination of coverage and the notifications will take place in PAHub.

**Continuity of Care – Classes of Clinical Concern**

For initial requests, Geisinger Health Plan will not require members to meet prior authorization or step therapy criteria if they are currently taking a medication in one of the following drug classes:

- Immunosuppressants (for prophylaxis of organ transplant rejection)
- Antidepressants
- Antipsychotics
- Anticonvulsants
- Antiretrovirals
- Antineoplastics
- Tumor Necrosis Factor Blockers
- Multiple Sclerosis
- Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder

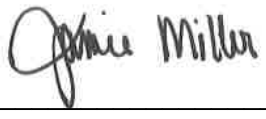
If members are currently receiving one of these medications requests for coverage will be approved as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**Continuity of Care – All Others**

Requests for continuity of care for all other medications will be at the discretion of the reviewer and may be considered if being used for a medically acceptable indication and the member is stable on therapy.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Geisinger

**POLICY NUMBER: 3.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Geisinger Health Plan (GHP) Formulary Exception**

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/99 |
| Reviewed: | 7/99 |
| Revised: | 7/99 |
| Reviewed: | 11/00 |
| Revised: | 3/01 |
| Revised: | 10/01 |
| Revised: | 11/01 |
| Revised: | 12/01 |
| Revised: | 5/02 |
| Revised: | 6/02 |
| Revised: | 10/02 |
| Revised: | 12/02 |
| Reviewed: | 1/03 – DOH approved |
| Reviewed: | 1/04 |
| Revised: | 3/04 – updated the name of Policy #02 on pg. 1 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Revised: | 4/09 – clarified 48 business hours |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 1/30/12 – changed title and signature |
| Reviewed: | 1/30/13 – annual review |
| Reviewed: | 1/30/14 – annual review |
| Revised: | 1/30/15 – annual review, updated signature |
| Reviewed: | 6/1/15 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 6/1/16 – annual review |
| Revised: | 6/1/17 – annual review, update standard Marketplace timeline |
| Revised: | 6/1/18 – annual review, updated hours & sig., added continuity of care language, updated procedure 6 |
| Revised: | 8/24/18 – updated notification, verbal and written, will be within the specified time frame from the request date. |
| Revised: | 3/13/19 – moved policy from technical/operational to Commercial Clinical policies |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 8/6/20 – updated date received definition, added written notification date definition, added activity log to PA Hub definition |
| Revised: | 8/10/20 – added CPhT and LPN definitions, added LPN as a reviewer |
| Revised: | 3/1/21 – annual review, updated logo, added CHIP timeline, corrected typo |
| Revised: | 3/1/22 – annual review, clarified can be made by member or healthcare provider in policy section, updated referenced policies |
| Revised: | 4/6/22 – replaced COC for all others with updated language |
| Revised: | 3/1/23 – annual review, removed language regarding 15 day timeline |
| Revised: | 3/1/24 – annual review; updated standard timeline to 48 hours; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 8.0**

**SECTION: Commercial Drug**
**SUBJECT: Ramelteon, Doxepin (generic Silenor), and Sublingual Zolpidem**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ramelteon, doxepin (generic Silenor), and sublingual zolpidem for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of ramelteon or doxepin (generic Silenor) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic insomnia, defined as a history of insomnia greater than or equal to two (2) months **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to use of formulary agents zolpidem (including controlled-release forms) **AND** eszopiclone **AND** zaleplon

A formulary exception for coverage of Sublingual Zolpidem (generic Intermezzo) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: eszopiclone **OR** zaleplon **OR** zolpidem immediate-release **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to zolpidem CR

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved ramelteon, doxepin (generic Silenor), or sublingual zolpidem will be paid for under the member's prescription drug benefit.

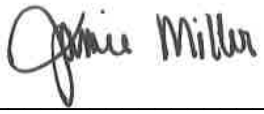
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

eszopiclone, estazolam, temazepam, zolpidem, zolpidem CR, zaleplon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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| Devised: | 7/99 |
| Effective: | 7/99 |
| Revised: | 12/99 |
| Reviewed: | 12/99 |
| Reviewed: | 11/00 |
| Revised: | 3/01 |
| Revised: | 2/02 |
| Reviewed: | 4/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05-updated title |
| Revised: | 3/06-updated title |
| Revised: | 4/06-updated criteria for coverage of this class of drugs |
| Reviewed: | 3/07 |
| Revised: | 4/07 added signature |
| Revised: | 8/07 corrected typo |
| Reviewed: | 3/08 – annual review |
| Revised: | 4/09 – annual review – updated alt (zaleplon) |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review, updated with generic Ambien & removed old criterion |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/6/12 – fixed typo, zolpidem CR missing ** |

| | |
|---|---|
| Revised: | 3/29/12 – added Intermezzo to policy |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo |
| Revised: | 3/1/14 – annual review, updated formatting, changed ER to CR for zolpidem |
| Revised: | 3/1/15 – annual review, updated signature, update Lunesta to eszopiclone |
| Revised: | 4/13/15 – removed PA from eszopiclone |
| Revised: | 7/22/15 – added Silenor to policy, updated criteria to require failure on eszopiclone |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – removed copay per 15 requirement, removed QL indicator from FA |
| Revised: | 5/1/16 – updated format, logo, and procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated Intermezzo to sublingual zolpidem |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Rozerem to generic ramelteon |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/18/20 – updated Silenor to generic |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

| Geisinger | POLICY NUMBER: 9.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Brand |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for brands that have a generic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of a branded (formulary) medication, for which there is an AB-rated generic, may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on or intolerance to the generic formulary agent(s) **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

**AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to up to three (3) formulary alternatives, if available

If an exception is made, the branded medication will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

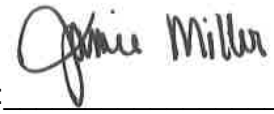
**FORMULARY ALTERNATIVES:**

AB-rated generics as listed in the Formulary

| Geisinger | POLICY NUMBER: 9.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Brand |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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| Devised: | 7/99 |
| Effective: | 7/99 |
| Revised: | 12/99 |
| Reviewed: | 12/99 |
| Reviewed: | 12/00 |
| Revised: | 3/01 |
| Revised: | 2/02 |
| Reviewed: | 6/02 |
| Revised: | 6/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 -updated title |
| Revised: | 3/06-updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review; clarified introduction |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 5/28/14 – updated to require failure on generic & failure on FA, updated signature |
| Revised: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, and procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |

Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 22.0**

**SECTION: Commercial Drug**
**SUBJECT: Linezolid**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for linezolid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***VRE*** – Vancomycin-resistant *Enterococcus*
7. ***MRSA*** – Methicillin resistant *Staphylococcus aureus*
8. ***MSSA*** – Methicillin susceptible *Staphylococcus aureus*

**PROCEDURE:**

A formulary exception for coverage of linezolid may be made for members who meet the following criteria:

- Medical record documentation of Vancomycin-Resistant *Enterococcus* (VRE) *faecium* infection which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of nosocomial pneumonia caused by *Staphylococcus aureus* (MSSA and MRSA) or *Streptococcus pneumoniae* which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of complicated skin and structure infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (MSSA and MRSA), *Streptococcus pyogenes*, or *Streptococcus agalactiae* which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (MSSA only) which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of community acquired pneumonia caused by *Streptococcus pneumonia* or *Staphylococcus aureus* (MSSA only) which has been diagnosed and documented with infectious disease consultation

**AND**

- Medical record documentation of culture and sensitivity showing the member's infection is not susceptible to alternative antibiotic treatments **OR**

- Medical record documentation of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that linezolid therapy was started during an inpatient setting

**For linezolid oral tablet requests exceeding 56 days of therapy in 180 days:**

- Medical record documentation of an infectious disease consultation documenting continued need of linezolid therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**AUTHORIZATION DURATION:** 28 days

If a formulary exception is approved linezolid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/01
Effective: 2/01

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 22.0**

**SECTION: Commercial Drug**
**SUBJECT: Linezolid**

| | |
|---|---|
| Revised: | 3/01 |
| Revised: | 2/02 |
| Reviewed: | 4/02 |
| Revised: | 6/02 |
| Revised: | 1/03 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05- updated title |
| Revised: | 3/06—updated title |
| Reviewed: | 3/07 |
| Revised | 5/07-removed vancomycin failure requirement |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11—annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated policy title to linezolid based on generic availability |
| Revised: | 3/25/16 – updated nosocomial pneumonia bullet, complicated skim & structure infections, uncomplicated skin & structure infections, added community acquired pneumonia, added culture & sensitivity requirements |
| Revised: | 5/1/16 – updated format, logo, and procedure |
| Revised: | 7/8/16 – corrected 2 typos in CAP criterion, corrected typo in definition |
| Revised: | 7/27/16 – added language for tablet QL exceptions |
| Revised: | 3/1/17 – annual review, corrected typo in definitions |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 27.0**

**SECTION: Commercial Drug**
**SUBJECT: Edarbi and Edarbyclor**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Edarbi and Edarbyclor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***ACE –*** angiotensin converting enzyme
7. ***HCT –*** hydrochlorothiazide

**PROCEDURE:**

An exception for coverage of Edarbi or Edarbyclor may be made for individuals who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary angiotensin receptor blockers

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: one tablet per day

If a formulary exception is approved Edarbi or Edarbyclor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**ARB:** candesartan, losartan, irbesartan, olmesartan, telmisartan, valsartan
**ARB/diuretic combinations:** candesartan/hctz, irbesartan/hctz, losartan/hctz, olmesartan/hctz, telmisartan/hctz, valsartan/hctz
**ACE inhibitors:** benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, trandolapril, ramipril

**ACE inhibitors/diuretic combinations:** captopril/hctz, benazepril/hctz, enalapril/hctz, lisinopril/hctz, moexipril/hctz

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Effective: 5/01
Devised: 3/01
Reviewed: 6/01
Revised: 7/01
Revised: 9/01
Revised: 12/01
Revised: 5/02
Revised: 3/03
Revised: 4/03 Cozaar criteria updated to reflect revised QIC guidelines
Revised: 3/04 – updated formulary alternatives
Revised: 3/05 – updated title
Revised: 3/06 – updated criteria and title
Revised: 3/07 – updated generics
Revised: 4/07 – added signature
Revised: 3/08 – annual review, updated alternatives
Revised: 4/09 – annual review, Cozaar removed
Revised: 7/09 – added other ARB's, updated criteria
Revised: 8/09 – fixed typo
Reviewed: 3/10 – annual review
Revised: 4/10 – updated alternatives
Revised: 3/1/11 – annual review-updated alternative section
Revised: 2/2/12 – added Edarbi to policy
Revised: 3/1/12 – annual review, updated sig, removed Teveten & Teveten HCT
Revised: 3/29/12 – added Edarbyclor to policy
Revised: 3/1/13 – annual review, updated logo and definitions, removed Avapro and Avalide, changed Atacand HCT to candesartan HCT, changed Diovan HCT to

valsartan HCT, updated title
Revised: 7/29/13 – removed generic valsartan/hctz & added Diovan HCT, updated criteria for Diovan HCT
Reviewed: 3/1/14 – annual review
Revised: 12/1/14 – added failure of irbesartan or irbesartan/hctz, updated alternatives, updated signature
Revised: 3/1/15 – annual review, updated Micardis to telmisartan, updated Micardis HCT to telmisartan HCT, removed Diovan HCT from policy, updated Atacand to candesartan, updated Diovan to valsartan
Revised: 9/19/15 – added failure of valsartan, updated Micardis to telmisartan, removed valsartan from policy name, removed Diovan references, updated FA
Revised: 5/1/16 – updated format, logo, and procedure
Revised: 3/1/17 – annual review, updated Benicar to generic, updated FA formatting
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, removed candesartan, candesartan/hctz, olmesartan, olmesartan/hctz, telmisartan, and telmisartan/hctz from policy, updated FA
Revised: 5/29/19 – updated criteria to failure of 3 preferred ARBs, added QL, corrected typo, deleted note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, added QL note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 29.0**

**SECTION: Commercial Drug**
**SUBJECT: Human Growth Hormone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for human growth hormone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Coverage for human growth hormone is available for members of Geisinger Health Plan who meet the following criteria:

**For Norditropin:**

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication

**For all other Growth Hormone Agents:**

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Norditropin* (if applicable)

**MEDISPAN AUTHORIZATION LEVEL:**

- Norditropin GPI-14 (enter all): 3010002000D212, 3010002000D230, 3010002000D240, 3010002000D260
- Genotropin, Humatrope, Ngenla, Nutropin AQ, Saizen, Serostim, Skytrofa, Sogroya, Zomacton: GPI-12
- Omnitrope GPI-12 (enter all): 301000200021, 970510501063

**AUTHORIZATION DURATION:**

Authorization for Growth Hormone will be for a time period of one year. Continuation of coverage will be provided based on medical record documentation to determine if there is appropriate follow up care with the physician, if any endpoint criteria are met, or if any major change in clinical status has occurred.

**FDA Approved Indications:**
**Pediatric Growth Hormone Deficiency:** Norditropin, Genotropin, Humatrope, Ngenla, Nutropin AQ, Omnitrope, Saizen, Skytrofa, Sogroya, Zomacton

**Prader-Willi syndrome:** Norditropin, Genotropin, Omnitrope

**Small for Gestational Age (SGA):** Norditropin, Genotropin, Humatrope, Omnitrope, Zomacton

**Turner syndrome:** Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Zomacton

**Idiopathic short stature:** Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Zomacton

**Short stature homeobox-containing gene (SHOX) deficiency:** Humatrope, Zomacton

**Noonan syndrome:** Norditropin

**Growth Failure Secondary to Chronic Kidney Disease:** Nutropin AQ

**Adult Growth Hormone Deficiency:** Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Sogroya, Zomacton

**HIV patients with wasting or cachexia:** Serostim

**Short bowel syndrome**: Zorbtive

If an exception is made, human growth hormone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

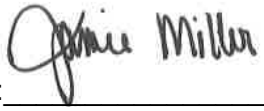
**FORMULARY ALTERNATIVES:**
Norditropin*

*prior authorization required

| Geisinger | POLICY NUMBER: 29.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Human Growth Hormone |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/97
Revised: 1/99
Reviewed: 12/00
Revised: 3/01
Revised: 2/02
Revised: 4/02
Revised: 3/03
Revised: 3/04 – removed Vitaline requirement
Revised: 3/05 – updated title
Revised: 6/05 – entire policy updated as a result of April P&T
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 4/10 – revised policy as a result of addition of preferred agents
Revised: 9/10 – revised policy to include FDA approved indications
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 1/25/13 – updated FDA approved indications
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, update signature
Revised: 3/1/16 – annual review, removed Accretropin, Nutropin, & Tev Tropin (no longer available), removed HumatroPen (device) added Zomacton, updated current FDA approved indications
Revised: 5/1/16 – updated format, logo, and procedure, updated preferred agent from Genotropin to Nutropin, updated FA
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added PA indicator to FA
Revised: 4/6/18 – removed Nutropin as a preferred agent, updated FDA indications, updated FA
Revised: 2/6/19 – updated FDA approved indications for Zomacton

Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, removed coinsurance statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/4/22 – added Skytrofa
Reviewed: 3/1/23 – annual review
Revised: 11/1/23 – updated signature title; added Sogroya to policy
Revised: 2/12/24 – added Ngenla to policy
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 30.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Topical Tretinoin Cream and Gel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for topical tretinoin cream and gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of topical tretinoin cream or gel may be made for members who meet the following criterion:

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult onset acne

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, IGNORE AGE HANDLER only, and generic only

**NOTE: Authorization not needed for members less than 30 years of age. Policy does not apply to tretinoin microsphere gel.**

If an exception is made, topical tretinoin cream or gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

benzoyl peroxide, clindamycin, erythromycin, erythromycin and clindamycin gel, erythromycin and benzoyl peroxide gel, isotretinoin, sulfacetamide and sulfur lotion, tetracycline

| Geisinger | POLICY NUMBER: 30.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Topical Tretinoin Cream and Gel |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/97
Reviewed: 3/01
Revised: 3/01
Revised: 2/02
Reviewed: 4/02
Revised 3/03
Reviewed: 03/04
Revised: 09/04 – updated Accutane to generic
Revised: 03/05 – updated title
Revised: 3/06 – updated title
Revised: 3/07 – updated generics
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Revised: 8/09 – added gel
Reviewed: 3/10 – annual review, added alt of generic Benzaclin
Reviewed: 3/1/11—annual review
Revised: 3/1/12 – annual review, updated sig, added Retin A MicroGel
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated formatting, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, and procedure
Revised: 3/1/17 – removed Retin A MicroGel
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added OAL
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated to cream/gel only; updated authorization level; updated

signature title

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 32.0**

**SECTION: Commercial Drug**
**SUBJECT: Coverage of Compounded Prescriptions**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for compounded prescriptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Coverage of compounded prescriptions is available if the following criteria are met:

- The compounded medication does not contain any excluded active ingredients **AND**
- The safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to formulary alternatives

****An authorization should only be entered for approved, non-excluded compound ingredients.**

****If the compound contains ingredients that are excluded from coverage, the dispensing pharmacy has the ability to enter submission clarification code (SCC) 08 in order to be reimbursed for all covered products.**

****If none of the ingredients being compounded requires a prescription to be dispensed, the compounded prescription is excluded from coverage. ****

****Compounds of products that have not received FDA approval or for a diagnosis for which there is no FDA approved treatment indication are excluded from coverage (i.e., natural hormones).****

****Certain compounds will require a prior authorization if a certain cost threshold is met.****

| Geisinger | POLICY NUMBER: 32.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Coverage of Compounded Prescriptions |

****Claims for compounded prescriptions must be submitted at the point of service through the electronic claims processing system and will be paid based on the calculated ingredient cost.****

If an exception is made, the compounded prescription will be paid for under the member's prescription drug benefit.

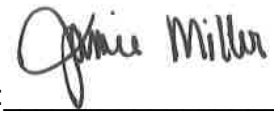
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/97 |
| Reviewed: | 3/98 |
| Reviewed: | 3/99 |
| Reviewed: | 12/00 |
| Revised: | 3/01 |
| Revised: | 4/01 |
| Revised: | 2/02 |
| Revised: | 5/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 8/04 – updated verbiage |

| | |
|---|---|
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review—updated informational section |
| Revised: | 3/1/12 – annual review and updated signature |
| Revised: | 9/17/12 – updated criteria for coverage and updated location |
| Revised: | 3/1/13 – annual review, updated logo and definitions, corrected signature title |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated payment logic to reflect pay as calculated |
| Revised: | 5/1/16 – updated format, logo, and procedure |
| Revised: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, defined FDA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; added note regarding SCC 8 and auth for covered only; updated signature title |

Geisinger

**POLICY NUMBER: 33.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Itraconazole**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for itraconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

**Coverage of itraconazole for the treatment of onychomycosis is not a covered service under the prescription benefit.**

**Itraconazole** coverage is available if **all** of the following criteria are met:

- Medical record documentation of **one or a combination** of the following diagnoses:
  - Dermatomycoses due to tinea corporis, tinea cruris, tinea pedis, or pityriasis versicolor
  - Invasive pulmonary aspergillosis
  - Noninvasive pulmonary aspergillosis
  - Extrapulmonary aspergillosis
  - Oral candidiasis
  - Oral/esophageal candidiasis
  - Chronic pulmonary histoplasmosis
  - Cutaneous sporotrichosis
  - Lymphatic sporotrichosis
  - Paracoccidioidomycosis
  - Chromomycosis
  - Blastomycosis **AND**
- Medical record documentation of a positive culture substantiating the diagnosis and/or diagnoses

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, itraconazole will be paid for under the member’s prescription drug benefit.

| Geisinger | POLICY NUMBER: 33.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Itraconazole |

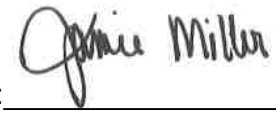
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/98 |
| Reviewed: | 3/99 |
| Reviewed: | 6/01 |
| Revised: | 7/01 |
| Revised: | 10/01 |
| Revised: | 6/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Revised: | 3/07 – updated generic itraconazole |
| Revised: | 4/07 – added signature |
| Revised: | 7/07 – updated generic (terbinafine) |
| Reviewed: | 3/08 – annual review |
| Revised: | 5/08 – changed “drug rider” to “benefit” |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review and update signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, removed terbinafine from policy, updated signature |

| | |
|---|---|
| Revised: | 3/1/16 – annual review, updated bullet formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure, removed terbinafine |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 6/2/17 – added extrapulmonary aspergillosis |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 36.0**

**SECTION: Commercial Drug**
**SUBJECT: Dexlansoprazole & Omeprazole/ Sodium Bicarbonate Capsules**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for dexlansoprazole and omeprazole/sodium bicarbonate capsules for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for the coverage of **dexlansoprazole** may be made for members who meet the following criterion:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of omeprazole **AND** pantoprazole **AND** lansoprazole **AND** rabeprazole **AND** esomeprazole, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**

- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on the maximal doses of omeprazole, pantoprazole, lansoprazole, rabeprazole, and esomeprazole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

An exception for the coverage of **Omeprazole/Sodium Bicarbonate Capsules** may be made for members who meet the following criterion:

- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on the maximal doses of omeprazole, pantoprazole, lansoprazole, rabeprazole, dexlansoprazole*, and esomeprazole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, dexlansoprazole or omeprazole/sodium bicarbonate capsules will be paid for under the member's prescription drug benefit.

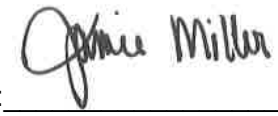
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/01 |
| Effective: | 10/01 |
| Revised | 2/02 |
| Reviewed: | 5/02 |
| Revised: | 6/02 |
| Reviewed: | 1/03 |
| Revised: | 1/03 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 6/05 – added Zegerid to policy |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Revised: | 7/07 – added step criteria |
| Revised: | 10/07 |
| Reviewed: | 3/08 – annual review |

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| Revised: | 6/08 – removed step therapy reference |
| Revised: | 7/08 – changed Protonix to pantoprazole |
| Reviewed: | 4/09 – annual review |
| Revised: | 11/09 – added Kapidex |
| Revised: | 1/10 – updated quantity limit for Kapidex |
| Reviewed: | 3/10 – annual review |
| Revised: | 4/10 – updated name change for Kapidex to Dexilant |
| Revised: | 9/10 – added generic Zegerid (omeprazole/sodium bicarbonate) to policy |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated title, removed Kapidex |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 12/9/14 – removed Aciphex from policy, added failure of rabeprazole to all drugs included in policy, updated alternatives, updated signature |
| Revised: | 3/1/15 – annual review, removed Aciphex from Policy section 1 |
| Revised: | 9/19/15 – updated Nexium to esomeprazole, removed failure of Dexilant from esomeprazole, added failure of esomeprazole to Dexilant, updated FA |
| Revised: | 3/1/16 – updated Nexium to esomeprazole in Zegerid criterion, updated quantity limit formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed brand name Zegerid |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 10/8/18 – removed PA from esomeprazole |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL language |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Dexilant to generic |
| Revised: | 3/1/23 – annual review; added ST language and generic only to dexlansoprazole |
| Revised: | 4/7/23 – removed order of failure requirement, updated signature title |
| Revised: | 7/25/23 – moved omeprazole/sodium bicarb packets to policy 753; removed “in that order” from criteria |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 41.0**

**SECTION: Commercial Drug**
**SUBJECT: Enbrel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Enbrel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of adult rheumatoid arthritis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg syringe/pen: 4 mL per 28 days
  - 25 mg syringe: 4 mL per 28 days
  - 25 mg vial: 8 vials per 28 days

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

azathioprine, cyclosporine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, Depen, Ridaura

**For treatment of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of both NSAID therapy **AND** methotrexate or other DMARD if methotrexate therapy is contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Enbrel is <u>not</u> being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg syringe/pen: 4 mL per 28 days
  - 25 mg syringe: 4 mL per 28 days
  - 25 mg vial: 8 vials per 28 days

**FORMULARY ALTERNATIVES:**
methotrexate, sulfasalazine

**For the treatment of Psoriatic Arthritis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of one of the following:
    - For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 50 mg syringe/pen: 4 mL per 28 days
    - 25 mg syringe: 4 mL per 28 days
    - 25 mg vial: 8 vials per 28 days

**FORMULARY ALTERNATIVES:**

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For the treatment of Juvenile Psoriatic Arthritis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of one of the following:
    - For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **OR**
    - For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that the prescribed dosing is appropriate for member's weight

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 50 mg syringe/pen: 4 mL per 28 days
    - 25 mg syringe: 4 mL per 28 days
    - 25 mg vial: 8 vials per 28 days

**FORMULARY ALTERNATIVES:**

methotrexate, celecoxib, diclofenac, diclofenac extended release, ibuprofen, etodolac extended release (Children ≥6 years weighing at least 20 kg), indomethacin, indomethacin sustained release (adolescents ≥15 years), ketorolac, meclofenamate (Adolescents ≥14 years), meloxicam, naproxen, naproxen sodium, naproxen EC, oxaprozin (children ≥6 years), piroxicam, sulindac, tolmetin

**For the treatment of ankylosing spondylitis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Physician documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDS) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg syringe/pen: 4 mL per 28 days
  - 25 mg syringe: 4 mL per 28 days
  - 25 mg vial: 8 vials per 28 days

**FORMULARY ALTERNATIVES:**
celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For the treatment of moderate to severe Plaque Psoriasis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation that Enbrel is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:**

- **Initial Request for Enbrel 50 mg syringe/pen, 25 mg syringe**
  - Add treat as "include" process modifier, ignore misc handler, max scripts 3, max script quantity 8, with a duration of 3 months
    - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 4 mL per 28 days
- **Initial Request for Enbrel 25 mg vial**
  - Add treat as "include" process modifier, ignore misc handler, max scripts 3, max script quantity 16, with a duration of 3 months
    - QL FOR LETTER: Loading dose: 16 mL per 28 days; Maintenance dose: 8 mL per 28 days
- **Renewal Requests** – *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
  - QL FOR LETTER ONLY:
    - 50 mg syringe/pen: 4 mL per 28 days

- 25 mg syringe: 4 mL per 28 days
- 25 mg vial: 8 vials per 28 days

**FORMULARY ALTERNATIVES:**

cyclosporine, methotrexate

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**For the treatment of pediatric Plaque Psoriasis:**
An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation that Enbrel is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) topical corticosteroids **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg syringe/pen: 4 mL per 28 days
  - 25 mg syringe: 4 mL per 28 days
  - 25 mg vial: 8 vials per 28 days

**FORMULARY ALTERNATIVES:**

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and

solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

If an exception is made, Enbrel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 10/01
Effective: 10/01
Revised: 1/02
Revised: 2/02
Revised: 3/03
Revised: 3/04 – updated criteria to coordinate with Medical Benefit Pharmaceutical Policy 6.0
Revised: 10/04 – updated criteria to include moderate to severe plaque psoriasis.
Revised: 3/05 – updated title
Revised: 6/05 – spelling error corrected.
Revised: 10/05 – updated for generic Arava availability
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Revised: 4/08 – changed psoriasis criteria to 10%
Revised: 5/08 – updated criteria
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/2012 – annual review updated signature
Revised: 9/17/2012 – updated authorization duration and updated location
Revised: 3/1/13 – annual review, updated logo & definitions, removed JIA criterion from RA
Revised: 5/4/13 – updated age restriction for JIA
Revised: 3/1/14 – annual review, updated formulary alternatives
Revised: 4/1/14 – removed “and administered” from RA prescriber criteria
Revised: 9/22/14 – updated clinical criteria for all indications (except PJIA) and alternative criteria for all indications, updated FA, updated signature, modified authorization duration wording for all indications, updated PJIA header.
Revised: 11/21/14 – from PJIA, removed wording regarding Humira’s age restrictions and removed, “For patients aged 4 years and older”
Revised: 2/9/15 – updated alternatives criteria for all indications, formulary alternatives, and prescriber criteria for PsA
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 3/1/16 – annual review, updated policy formatting to improve readability, added approval statement
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 3/27/17 – added pediatric psoriasis indication, peripheral vs. axial PsA, updated FA
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age and prescriber formatting
Revised: 5/30/18 – added combination with other biologic agents, added QL, updated failure to Cosentyx & Humira (PsA, AS, PP), defined 2 alternatives for pediatric PP, updated FA
Revised: 10/1/18 – removed failure of MTX & added failure of Humira for RA, updated RA FA
Reviewed: 3/1/19 – annual review, defined TNF, added QL approval note, added PA required for RA
Revised: 7/24/19 – added authorization parameters to PP
Revised: 09/25/19 – updated QL
Revised: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry for PP
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how adult PsO QL is entered
Revised: 7/20/22 – updated topical corticosteroid alternatives in pediatric PsO section
Revised: 1/1/23 – updated all indications & FA to allow Enbrel as initial biologic after failure of 1st line therapy
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title
Revised: 4/10/24 – added PSJIA; updated Medispan level for all indications; updated QL parameters for PsO

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 45.0**

**SECTION: Commercial Drug**
**SUBJECT: Pulmozyme**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pulmozyme for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Pulmozyme may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis (CF) **AND**
- Medical record documentation that Pulmozyme is prescribed by a pulmonologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Pulmozyme will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

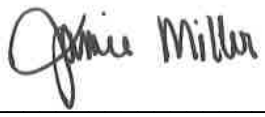
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 45.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Pulmozyme** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/99 |
| Effective: | 7/99 |
| Revised: | 10/01 |
| Revised: | 4/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added formulary alternative section |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 6/2/17 – removed age restriction |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 48.0**

**SECTION: Commercial Drug**
**SUBJECT: Inhaled Tobramycin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of inhaled tobramycin may be made for members who meet **all** of the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that tobramycin inhalation solution is prescribed by a pulmonologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for tobramycin inhalation solution include generic only.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tobramycin inhalation solution: 280 mL per 56 days
  - Tobi PodHaler: 224 mL per 56 days

If an exception is made, inhaled tobramycin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Bethkis*

*prior authorization required

| Geisinger | POLICY NUMBER: 48.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Inhaled Tobramycin |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/99 |
| Effective: | 7/99 |
| Revised: | 10/01 |
| Revised: | 2/02 |
| Revised: | 4/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated title based on generic availability |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 11/20/15 – updated title, added QL, added FA |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated inhalation solution QL |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 6/4/19 – removed CSR QL note, added authorization parameters |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 49.0**

**SECTION: Commercial Drug**
**SUBJECT: Darifenacin ER, Gemtesa, Oxytrol, Tolterodine ER, Fesoterodine ER, and Trospium XR**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for darifenacin ER, Gemtesa, Oxytrol, tolterodine ER, fesoterodine ER, and trospium XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of darifenacin ER, Gemtesa, Oxytrol, tolterodine ER, fesoterodine ER, or trospium XR may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to use of oxybutynin, oxybutynin XL or tolterodine **AND** solifenacin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for darifenacin ER, fesoterodine ER, tolterodine ER, or trospium XR include generic only.

If a formulary exception is approved darifenacin ER, Gemtesa, Oxytrol, tolterodine ER, fesoterodine ER, or trospium XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

oxybutynin, oxybutynin XL, solifenacin, tolterodine, Myrbetriq

Geisinger

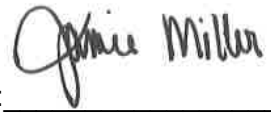
**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 49.0**

**SECTION: Commercial Drug**
**SUBJECT: Darifenacin ER, Gemtesa, Oxytrol, Tolterodine ER, Fesoterodine ER, and Trospium XR**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/99 |
| Effective: | 7/99 |
| Revised: | 10/01 |
| Revised: | 2/02 |
| Revised: | 3/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Revised: | 3/07 – updated title and generics |
| Revised: | 4/07 – added signature |
| Revised | 7/07 – added Enablex, Sanctura to title, Vesicare to alternatives |
| Revised: | 8/07 – added Oxytrol |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Revised: | 7/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/29/12 – added Anturol to policy |
| Revised: | 1/25/13 – added Myrbetriq to policy, removed Detrol from policy, updated title |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated title and generics |
| Revised: | 3/1/14 – annual review, updated formatting, updated Detrol LA to tolterodine ER |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Anturol, updated Enablex to darifenacin |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting |
| Revised: | 10/8/18 – removed Myrbetriq PA, updated FA |
| Reviewed: | 3/1/19 – annual review |

Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Vesicare to gen.
Revised: 7/1/21 – added Gemtesa
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review, updated Toviaz to fesoterodine
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 50.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Antihemophilic Agents for Hemophilia B**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for antihemophilic agents for hemophilia B for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of self-administered antihemophilic agents for hemophilia B may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia B (a documented Factor IX deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used for routine prophylaxis, on-demand treatment/control of bleeding episodes, **OR** perioperative management of bleeding

| | Routine Prophylaxis | On-Demand/ Perioperative |
|---|---|---|
| Alphanine SD | | X |
| Alprolix | X | X |
| Bebulin | | X |
| BeneFIX | | X |
| Idelvion | X | X |
| Ixinity | | X |
| Mononine | | X |
| Profilnine | | X |
| Rebinyn | | X |
| Rixubis | X | X |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, the antihemophilic agent for hemophilia B will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/99 |
| Effective: | 7/99 |
| Revised: | 10/01 |
| Revised: | 2/02 |
| Revised: | 6/02 |
| Revised: | 3/03 |
| Revised: | 3/04 – updated to reflect coverage changes |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Revised: | 4/09 – annual review; removed old renewal language |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |

Revised: 3/1/16 – annual review, added formulary alternatives section
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated formatting
Revised: 7/20/18 – updated policy/title to only include hemophilia B, updated diagnosis & indication criteria, added indication chart
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; corrected typo

Geisinger

**POLICY NUMBER: 63.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Elmiron**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Elmiron for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Elmiron may be made for members who meet **all** of the following criteria:

- Medical record documentation of a diagnosis of interstitial cystitis **AND**
- Medical record documentation that Elmiron is prescribed by a urologist or gynecologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Elmiron will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

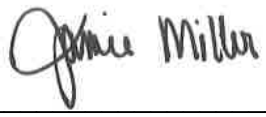
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 63.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Elmiron |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/02 |
| Effective: | 4/02 |
| Revised: | 7/02 |
| Revised: | 3/03 |
| Revised: | 3/04 – updated to reflect allowance of prescribing by a gynecologist |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added formulary alternatives section |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber formatting |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20- annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/23 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 67.0**

**SECTION: Commercial Drug**
**SUBJECT: Pimecrolimus Cream**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pimecrolimus cream for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of pimecrolimus cream may be made for members who meet **all** of the following criteria:

- Medical record documentation of a diagnosis of atopic dermatitis **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on at least two formulary topical corticosteroids unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) **or** (b) patient is between 2 and 15 years of age

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, pimecrolimus cream will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

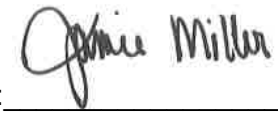
**FORMULARY ALTERNATIVES:**

tacrolimus ointment
**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide

0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/02
Effective: 4/02
Revised: 7/02
Revised: 3/03
Reviewed: 3/04
Revised: 10/04 – added Protopic ointment to the policy

| Geisinger | POLICY NUMBER: 67.0 |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Pimecrolimus Cream** |

Reviewed: 3/05
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Revised: 4/09 – updated criteria
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, corrected typo
Revised: 12/1/14 – removed requirement that RX be written by a specialist, updated signature
Revised: 3/1/15 – annual review, changed Protopic to Tacrolimus, removed **AND** from second criterion
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 8/8/17 – removed PA from tac. oint, added failure of tac. oint to Elidel, updated FA
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – renamed Elidel to generic pimecrolimus
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 7/20/22 – updated topical corticosteroid alternatives
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 71.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Kineret**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kineret for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For Rheumatoid Arthritis:**

A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Kineret is prescribed by a rheumatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of rheumatoid arthritis
- Medical record documentation that Kineret is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QLs must be entered within the authorization. Start date is the same for both authorizations.*

1. Add PE, OQL, DS max quantity dispensed 0.67, min day supply 28, max day supply 28
    - QL FOR LETTER: 0.67 ml per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on Kineret therapy is required.

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Rinvoq*, Xeljanz*

*prior authorization required

**For Neonatal-Onset Multisystem Inflammatory Disease**
A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) **AND**
- Medical record documentation that Kineret is prescribed by an immunologist, rheumatologist, or allergist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Neonatal-Onset Multisystem Inflammatory Disease on Kineret therapy is required.

**FORMULARY ALTERNATIVES:**
none

**For Cryopyrin-Associated Periodic Syndrome (CAPS)**
A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of diagnosis of Cryopyrin–Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation **AND**
- Medical record documentation that Kineret is prescribed by an immunologist, rheumatologist, or allergist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Cryopyrin-Associated Periodic Syndrome on Kineret therapy is required.

**FORMULARY ALTERNATIVES:**
none

**For Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**
A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL1RN (Interleukin 1 Receptor Antagonist gene) **AND**
- Medical record documentation that Kineret is prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Deficiency of Interleukin-1 Receptor Antagonist on Kineret therapy is required.

**FORMULARY ALTERNATIVES:**
none

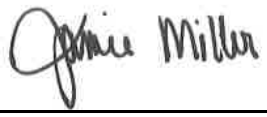
If a formulary exception is approved, Kineret will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 71.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Kineret** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/02
Effective: 7/02
Revised: 12/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 10/05 – updated for generic Arava availability
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Revised: 5/08 – updated criteria
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated sig
Revised: 9/17/12 – updated authorization duration and file location
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 5/4/13 – added NOMID indication
Revised: 3/1/14 – annual review, fixed typo, updated formatting
Revised: 3/20/14 – updated RA criteria to require failure on Humira and Enbrel specifically
Revised: 9/22/14 – updated RA clinical & alternative criteria, updated RA auth duration wording, & updated FA to include only Humira & Cimzia, updated signature
Revised: 2/9/15 – updated RA criteria to require failure on Enbrel instead of Cimzia, added approval statement
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 3/1/16 – annual review, updated policy format to improve readability
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/27/17 – removed COE requirement from NOMID
Revised: 6/2/17 – updated format, added CAPS, added auth duration to NOMID
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated formatting
Revised: 10/1/18 – removed failure of Enbrel, updated FA, added concurrent biologic crit. (RA)
Revised: 3/1/19 – annual review, corrected typo, defined TNF
Revised: 5/29/19 – added QL to RA indication
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – corrected typo in CAPS header, added DIRA indication

Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated RA QL entry
Revised: 1/1/23 – updated to allow Kineret after failure of 2 preferred agents & FA for RA; added auth duration
Revised: 3/1/23 – annual review; updated auth parameters due to NF status and auth duration
Revised: 3/1/24 – annual review; updated signature title; updated formulary alternatives for RA

Geisinger

**POLICY NUMBER: 72.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Actimmune**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Actimmune for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Actimmune may be made for members who meet the following criterion:

- Medical record documentation of a diagnosis of chronic granulomatous disease **OR** osteopetrosis

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Actimmune will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

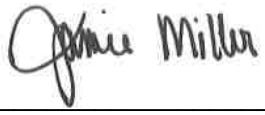
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 72.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Actimmune** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/02 |
| Effective: | 10/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 73.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sirolimus**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sirolimus for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of sirolimus may be made for members who meet **all** of the following criteria:

**Renal Transplant**

- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of a renal transplant

**Lymphangioleiomyomatosis**

- Medical record documentation of a diagnosis of lymphangioleiomyomatosis

**Graft vs. Hose Disease Prophylaxis**

- Medical record documentation of use for graft versus host disease prophylaxis **AND**
- Medical record documentation of treatment with a calcineurin inhibitors **AND** one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate or mycophenolate mofetil **OR**
    - Use of triple therapy with a calcineurin inhibitor, methotrexate or mycophenolate mofetil, and sirolimus

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

If an exception is made, sirolimus will be paid for under the member's prescription drug benefit.

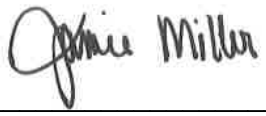
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Renal Transplant: azathioprine, cyclosporine, mycophenolate, tacrolimus
Graft versus Host Disease: methotrexate, mycophenolate mofetil

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/02 |
| Effective: | 10/02 |
| Revised: | 3/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 –updated title |
| Reviewed: | 3/07 |
| Revised: | 4/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Revised: | 3/10 – annual review, updated alternatives |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, added sirolimus tablets to policy, updated signature |
| Revised: | 7/22/15 – added lymphangioleiomyomatosis indication, updated formulary alternatives |

| | |
|---|---|
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated formatting |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/9/20 – added GVHD prophylaxis |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated all references to Rapamune solution to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 83.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lumigan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lumigan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Lumigan may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan), tafluprost, **AND** travoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost (generic Xalatan), tafluprost, **AND** travoprost

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Lumigan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

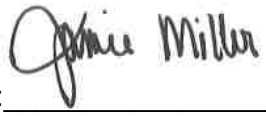
latanoprost (generic Xalatan), travoprost, tafluprost (generic Zioptan)*

*prior authorization required

| Geisinger | POLICY NUMBER: 83.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Lumigan |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/03
Effective: 1/03
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 7/18/12 – added Zioptan to policy, changed Travatan to Travatan Z
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 7/29/13 – updated alternatives to include travoprost
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 12/22/17 – removed Rescula (obsolete), updated signature
Reviewed: 3/1/18 – annual review
Revised: 5/30/18 – removed travoprost
Revised: 8/21/18 – removed PA from Zioptan, updated Lumigan to step, added failure of Zioptan, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Travatan to generic, updated formulary alternatives

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review, updated Zioptan to generic
Revised: 3/1/24 – annual review; updated signature tite

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 84.0**

**SECTION: Commercial Drug**
**SUBJECT: Humira, Adalimumab-FKJP, Hadlima, and Yusimry**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Humira, adalimumab-FKJP, Hadlima and Yusimry for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For Adult Rheumatoid Arthritis**

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that adalimumab is prescribed by a rheumatologist **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that adalimumab is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that the member has been compliant with BIWEEKLY administration of adalimumab **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of adalimumab **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- **Biweekly Dosing**
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
        - QL for letter: 2 per 28 days
- **Weekly Dosing –**
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099
        - QL FOR LETTER: 4 per 28 days

**FORMULARY ALTERNATIVES:**

azathioprine, cyclosporine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, Depen, Ridaura

**For treatment of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis**
An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that adalimumab is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of both nonsteroidal anti-inflammatory drug (NSAID) therapy **AND** methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate therapy is contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- **Biweekly Dosing**
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
        - QL FOR LETTER: 2 per 28 days

**FORMULARY ALTERNATIVES:**

methotrexate, sulfasalazine

**For Psoriatic Arthritis**

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that adalimumab is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- **For peripheral disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
- **For axial disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- **Biweekly Dosing**
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
        - QL FOR LETTER: 2 per 28 days

**FORMULARY ALTERNATIVES:**
methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For Ankylosing Spondylitis**
An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Physician documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDS) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- **Biweekly Dosing**
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
        - QL FOR LETTER: 2 per 28 days

**FORMULARY ALTERNATIVES:**

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For Crohn's Disease**
An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet the following criteria:

- Medical record documentation that adalimumab is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**

- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of adalimumab **AND**
- Medical record documentation that the member has been compliant with BIWEEKLY administration of adalimumab **AND**
- Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines

**NOTE:**

- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adilimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:**

- **Adults and pediatrics > 40 kg: 160 mg on day 1, 80 mg 2 weeks later, then 40 mg biweekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, OQL, max quantity 6, max day supply 28, max script 1 for a 3 week authorization duration
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Pediatrics < 40 kg: 80 mg on day 1, 40 mg 2 weeks later, then 20 mg biweekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 80 mg on day 1, 40 mg 2 weeks later; Maintenance dose: 20 mg every other week (2 pens/syringes per 28 days)
- **Weekly Dosing –** *QL must be entered within the authorization.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099
        - QL FOR LETTER: 4 per 28 days

**FORMULARY ALTERNATIVES:**
Corticosteroids: prednisone, budesonide
Immunomodulators: azathioprine, 6-mercaptopurine

**For the treatment of moderate to severe Plaque Psoriasis**
An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:** *Two authorizations must be entered.*

- **80 mg on day 1, then 40 mg biweekly**
    1. In NCRX: Add PA, OQL, max quantity 4, max day supply 28, max script 1 for a 3 week authorization duration
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)

**FORMULARY ALTERNATIVES:**

cyclosporine, methotrexate

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam (Temovate/Clobex/Olux); diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E); fluocinonide 0.1% cream (Vanos); halobetasol 0.05% cream and ointment (Ultravate)

**For Ulcerative Colitis**
An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that adalimumab is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (azathioprine or 6-mercaptopurine (6-MP)) **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that adalimumab is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g., 6-mercaptopurine or azathioprine) **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of one of the following:
    - For an adult:
        - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of adalimumab **AND**
        - Medical record documentation that the member has been compliant with BIWEEKLY administration of adalimumab **AND**
        - Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines

      **OR**

        - Medical record documentation that weekly dosing was initiated prior to the member turning 18 years and the member is well-controlled on this dose
    - For a member less than or equal to 18 years of age:
        - Medical record documentation that the member is less than 18 years of age and receiving an appropriate dose based on body weight

**NOTE:**

- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT:**

- **Adults: 160 mg on day 1, 80 mg 2 weeks later, then 40 mg biweekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, OQL, max quantity 6, max day supply 28, max script 1 for a 3 week authorization duration
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)

- **Adult Weekly Dosing –** *QL must be entered within the authorization.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099
        - QL FOR LETTER: 4 per 28 days
- **Pediatrics 20 kg to 40 kg: 80 mg on day 1, 40 mg on day 8 and day 15, then 40 mg every other week –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 80 mg on day 1, 40 mg on day 8 and day 15; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Pediatrics greater than 40 kg: 160 mg on day 1, 80 mg on day 8 and day 15, then 40 mg every week –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg on day 8 and day 15; Maintenance dose: 40 mg every week (4 pens/syringes per 28 days)

**FORMULARY ALTERNATIVES:**
azathioprine, 6-mercaptopurine

**For Hidradenitis Suppurativa (HS)**
An exception for coverage of **WEEKLY administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of moderate to severe hidradenitis suppurativa (HS), defined as Stage II or III on the Hurley staging system* **AND**
- Medical record documentation of at least 3 abscesses or inflammatory nodules **AND**
- Medical record documentation of concomitant use of oral or systemic antibiotics **AND**
- Medical record documentation that the member has received counseling on weight management (if overweight) and smoking cessation (if the member is an active smoker) **AND**
- For members 12 to 18 years of age weighing 30 to less than 60 kg: medical record documentation of adalimumab being dosed at a maximum dose of 40 mg every other week **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

*Hurley staging system:
- Stage I: A single lesion without sinus tract formation.
- Stage II: More than one lesion or area, but with limited tunneling.
- Stage III: Multiple lesions, with more extensive sinus tracts and scarring.

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.
- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT FOR INITIAL APPROVALS:**

- **Adults & Age 12 – 18 years weighing ≥ 60 kg: 160 mg on day 1, 80 mg 2 weeks later, then 40 mg weekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, OQL, max quantity 6, max day supply 28, max script 1 for a 3 week authorization duration
    2. In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every week (4 pens/syringes per 28 days)
- **Adults & Age 12 – 18 years weighing ≥ 60 kg: 160 mg on day 1, 80 mg 2 weeks later, then 80 mg biweekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
        - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 80 mg every other week (2 pens/syringes per 28 days)
- **Age 12 – 18 years weighing 30 to < 60 kg: 80 mg on day 1, then 40 mg biweekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2 with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)

**FORMULARY ALTERNATIVES:**

none

**For the treatment of Non-Infectious Intermediate, Posterior and Panuveitis**
An exception for coverage of **BIWEEKLY (every other week) administration** of Humira, adalimumab-FKJP, Hadlima, or Yusimry may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by an ophthalmologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of non-infectious intermediate, posterior or panuveitis **AND**
- Medical record documentation of:
    - Therapeutic failure on, intolerance to, or contraindication to local/systemic corticosteroids **AND** an immunosuppressant (methotrexate, azathioprine, mycophenolate, cyclosporine, or tacrolimus) **OR**
    - For members 2-18 years of age: therapeutic failure on, intolerance to, or contraindication to local/systemic corticosteroids **AND** methotrexate **AND**
- For members 2-18 years of age: medical record documentation that adalimumab is being given in combination with methotrexate **OR** medical record documentation of contraindication to methotrexate **AND**
- Medical record documentation that member is receiving appropriate dose of adalimumab based on weight and age **AND**
- Medical record documentation that adalimumab is <u>not</u> being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Adalimumab is configured as a prior authorization for new starts only. Adalimumab will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** Select GHPHUMIRA Quick Code, no MediSpan authorization level required

**QUANTITY LIMIT FOR INITIAL APPROVALS:** *Two authorizations must be entered.*

- **Adult 80 mg on day 1, then 40 mg biweekly –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, OQL, max quantity 4, max day supply 28, max script 1 for a 3 week authorization duration
    2. In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Pediatric Uveitis –** *Two authorizations must be entered.*
    1. In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    2. In PA Hub: Add OQL, max quantity dispensed 2with an end date of 12/31/2099.
        - QL FOR LETTER: 2 per 28 days

**FORMULARY ALTERNATIVES:**

Immunosuppressants: methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus

Steroids: prednisone, methylprednisolone, dexamethasone, prednisolone, budesonide

If an exception is made, Humira, adalimumab-FKJP, Hadlima, or Yusimry will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/03 |
| Effective: | 1/03 |
| Revised | 7/03 – updated per July P&T Meeting |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 2/06 – updated qty limit |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 |
| Revised | 1/08 – update criteria for coverage |
| Reviewed: | 3/08 – annual review |
| Revised: | 5/08 – updated criteria |
| Revised: | 7/08 – added psoriasis criteria |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 6/21/12 – added criteria for ankylosing spondylitis |
| Revised: | 9/17/12 – updated authorization duration, changed rheumatoid arthritis to psoriatic arthritis under psoriatic arthritis reauthorization criteria |
| Revised: | 11/7/12 – added ulcerative colitis indication |
| Revised: | 3/1/13 – annual review, updated logo & definitions, fixed typo in Ankylosing Spondylitis |

Revised: 3/1/14 – annual review, updated formulary alternatives
Revised: 9/22/14 – updated criteria and formulary alternatives and auth duration for all indications, updated signature, added or capitalized AND between criteria for each indication
Revised: 11/21/14 – updated age criteria for PJIA and Crohn's, updated formulary alternative criteria and alternative list for PsA, removed weekly dosing criteria for PsA and PsO.
Revised: 2/9/15 – updated prescriber criteria for PsA
Reviewed: 3/1/15 – annual review
Revised: 7/22/15 – added dosing requirement to JRA, PsA, PsO, AS, UC, CD, removed failure of aminosalicylates from CD, added high risk criterion to CD, removed one copay per injection requirement, added review criteria under procedure, added quantity limits, moved formulary alternatives to each indication, updated formatting, added celecoxib to AS formulary alternatives
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 1/29/16 – added hidradenitis suppurativa indication
Revised: 3/1/16 – annual review, updated policy formatting
Revised: 3/23/16 – corrected typos in 1st and 5th bullets of HS criteria
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/18/16 – updated HS QL to reflect P&T approved recommendation
Revised: 11/22/16 – added Uveitis indication
Revised: 3/1/17 – annual review, updated HS auth duration to weekly, updated FA
Revised: 3/27/17 – axial vs. peripheral for PsA, updated FA
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated formatting, corrected typo
Revised: 5/30/18 – added combination with other biologic agents
Revised: 12/28/18 – updated initial RA auth duration, added weekly CD/UC criteria, updated CD/UC QL, added note to CD/UC, removed dosing criteria from biweekly CD/UC
Revised: 3/1/19 – annual review, defined abbreviations
Revised: 3/28/19 – added pediatric uveitis, updated adult uveitis alternative criteria, updated uveitis FA, updated uveitis prescriber to include rheumatologist, added pediatric HS
Revised: 5/24/19 – updated QL's to account for new strengths, package sizes, and CF formulation
Revised: 7/24/19 – added authorization parameters
Revised 9/17/19 – corrected initial auth duration to 1 week for CD, PP, UC, HS, and uveitis
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/13/20 – added weekly QL for UC
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statements
Revised: 3/26/21 – updated MediSpan approval level to GPI-10 for all indications
Revised: 6/8/21 – corrected adult HS QL in Darwin
Revised: 8/24/21 – UC Indication: changed age to 5 years, updated alternative requirements, added additional weekly dosing criteria, updated QL
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated QL entry
Revised: 7/20/22 – updated topical corticosteroid alternatives in PsO section
Reviewed: 3/1/23 – annual review
Revised: 7/25/23 – updated psoriasis FA; updated signature title
Revised: 2/12/24 – updated to include Humira, adalimumab-FKJP, Hadlima, or Yusimry; updated policy criteria from Humira to adalimumab; updated to NDC-9 due to biosimilar availability; updated QL's to match available formulations & auth entry in NCRx
Revised: 3/1/24 – annual review; updated auth entry to GHPHUMIRA Quick Code

| Geisinger | **POLICY NUMBER: 93.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Voriconazole** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for voriconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of voriconazole may be made for members who meet **ALL** of the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of invasive aspergillosis, esophageal candidiasis, or fungal infection caused by *Scedosporium apiospermum* or fungal infection caused by *Fusarium* species with an Infectious Disease consult, preferably with a culture report to back the diagnosis **OR**
- Medical record documentation of a diagnosis of candidemia in a non-neutropenic patient or disseminated candida infections of the skin, abdomen, bladder wall, kidney and wounds with failure on, intolerance to, or contraindication to IV amphotericin B and/or fluconazole as determined by Infectious Disease consult, preferably with a culture to back the diagnosis **AND**
- Medical record documentation of initiation of intravenous therapy with voriconazole in the hospital

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, voriconazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 93.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Voriconazole |

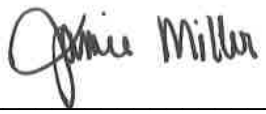
**FORMULARY ALTERNATIVES:**

itraconazole * (for applicable indications)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/03 |
| Effective: | 7/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 6/05 – added criteria #3 |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Revised: | 3/08 – annual review; updated alternatives |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature, clarified voriconazole and Vfend |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed brand name Vfend |
| Revised: | 6/2/17 – added esophageal candidiasis, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 93.0**

**SECTION: Commercial Drug**
**SUBJECT: Voriconazole**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 94.0**

**SECTION: Commercial Drug**
**SUBJECT: Stimulants for ADHD**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for stimulants for ADHD for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***ADHD*** – attention deficit hyperactivity disorder

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Adhansia XR, Adzenys XR-ODT, methylphenidate XR (generic Aptensio XR), Azstarys, Cotempla XR-ODT, methylphenidate transdermal patch (generic Daytrana), dexmethylphenidate HCl ER, dextroamphetamine solution, Dyanavel XR, Jornay PM, Mydayis, QuilliChew ER, Quillivant XR, methylphenidate HCl ER [OSM] 45 mg, 63 mg (generic Relexxii), Xelstrym, or Zenzedi 2.5 mg, 7.5 mg tablets may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CD$^{\Omega}$ **AND** amphetamine/dextroamphetamine SR combination

$^{\Omega}$ = **From the Metadate CD package insert, "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed."**

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for dextroamphetamine solution, methylphenidate XR (generic Aptensio XR), methylphenidate transdermal patch (generic Daytrana), methylphenidate HCl ER [OSM] 45 mg or 63 mg tablets (generic Relexxii), or dexmethylphenidate HCl ER include generic only.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - **Adhansia XR:** 1 capsule per day
  - **Adzenys XR-ODT:** 1 tablet per day
  - **Azstarys:** 1 capsule per day
  - **Cotempla XR-ODT 8.6 and 17.3 mg tablets:** 1 tablet per day
  - **Cotempla XR-ODT 25.9 mg tablets:** 2 tablets per day
  - **Dextroamphetamine 5 mg/5 mL solution:** 60 mL per day
  - **Dyanavel XR Tablets:** 1 tablet per day
  - **Jornay PM:** 1 capsule per day
  - **Methylphenidate HCl ER [OSM] 45 and 63 mg tablets:** 1 tablet per day
  - **Mydayis:** 1 tablet per day
  - **Xelstrym:** 1 patch per day
  - **Zenzedi 2.5 and 7.5 mg tablets:** 1 tablet per day

If an exception is made, Adhansia XR, Adzenys XR-ODT, methylphenidate XR (generic Aptensio XR), Azstarys, Cotempla XR-ODT, methylphenidate transdermal patch (generic Daytrana), dexmethylphenidate HCl ER, dextroamphetamine solution, Dyanavel XR, Jornay PM, Mydayis, QuilliChew ER, Quillivant XR, methylphenidate HCl ER [OSM] 45 mg, 63 mg (generic Relexxii), Xelstrym, or Zenzedi 2.5 mg, 7.5 mg tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD, guanfacine ER, atomoxetine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

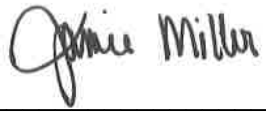
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 94.0**

**SECTION: Commercial Drug**
**SUBJECT: Stimulants for ADHD**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/03 |
| Effective: | 7/03 |
| Revised: | 3/04 – updated formulary alternative section |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Revised: | 3/07 – updated generics |
| Revised: | 5/07 – added signature |
| Revised: | 7/07 – added Daytrana, Focalin XR to policy, Adderall XR to alternatives |
| Revised: | 3/08 – annual review; updated alternatives |
| Revised: | 4/09 – annual review, updated alt. |
| Reviewed: | 3/10 – annual review |
| Revised: | 6/10 – updated criteria, added Concerta and Vyvanse to policy |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature, removed Ritalin LA & Concerta |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, added dexmethylphenidate HCl ER |
| Revised: | 7/22/15 – moved Vyvanse to policy 384.0 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, updated title, added guanfacine ER to FA |
| Revised: | 7/22/16 – added Aptensio XR, QuilliChew ER, and Quillivant XR to policy |
| Revised: | 3/1/17 – annual review, removed brand name Focalin XR |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting & FA, corrected typo, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 1/16/20 – added Adhansia XR and Jornay PM |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Aptensio to generic |
| Revised: | 1/4/22 – renamed policy, added Azstarys |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, added ADHD to definitions, corrected typo |
| Revised: | 12/5/22 – added Dyanavel XR tablet QL, linked Adzenys |
| Revised: | 3/1/23 – updated Daytrana to generic and added generic only approval requirement |
| Revised: | 4/7/23 – added Xelstrym to policy, updated signature title |
| Revised: | 7/25/23 – added Dyanavel & Adzenys to policy drug listing |
| Revised: | 11/1/23 – added Cotempla, dextroamphetamine solution, Mydayis, methylphenidate HCl ER [OSM] & Zenzedi to policy; added QL to Adzenys, Cotempla, dextroamphetamine solution, methylphenidate HCl ER [OSM], Mydayis, & Zenzedi |
| Reviewed: | 3/1/24 – annual review |

Geisinger Health Plan

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 95.0**

**SECTION: Commercial Drug**
**SUBJECT: Omnaris, Qnasl, and Zetonna**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Omnaris, Qnasl, and Zetonna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of **Omnaris**, **Qnasl, or Zetonna** may be made for members who meet the following criteria:

- Medical record documentation of failure on, contraindication to, or intolerance to fluticasone propionate, triamcinolone acetonide, **AND** mometasone furoate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Omnaris, Qnasl, or Zetonna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

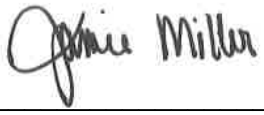
**FORMULARY ALTERNATIVES:**

fluticasone propionate, triamcinolone acetonide, mometasone furoate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger Health Plan | **POLICY NUMBER: 95.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Omnaris, Qnasl, and Zetonna** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/03 |
| Effective: | 7/03 |
| Reviewed: | 3/04 |
| Revised: | 12/04 – updated Beconase AQ criteria to include Nasonex being FDA approved for nasal polyps |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Revised: | 1/09 – added Omnaris |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 6/29/11 – removed Nasacort Aq, updated criteria and formulary alternatives |
| Revised: | 3/1/12 – annual review, updated signature, added Veramyst |
| Revised: | 7/18/12 – added Zetonna to policy |
| Revised: | 9/17/12 – added Qnasl to policy |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, update Nasonex to mometasone furoate |
| Revised: | 3/1/17 – annual review, updated Rhinocort to budesonide |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 7/16/19 – removed Veramyst from policy (product discontinued) |
| Revised: | 9/25/19 – removed budesonide from criteria and formulary alternatives (product discontinued) |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; removed Beconase AQ (discontinued) |

Geisinger

**POLICY NUMBER: 96.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lilly Insulin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to Lilly insulin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Lilly Insulin may be made for members who meet the following criteria:

- Medical record documentation that the requested insulin requires dilution **OR**
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to comparable Novo Nordisk brand insulin **(with the exception of Fiasp)**

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

If a formulary exception is approved, the requested Lilly Insulin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

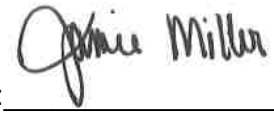
**FORMULARY ALTERNATIVES:**

Novo Nordisk Insulins (vials and pens): Novolin R, Novolin N, Novolin 70/30, Novolog, NovoLog Mix 70/30, Levemir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 96.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lilly Insulin** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/03 |
| Effective: | 10/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Revised: | 11/08 – added dilution criterion |
| Revised: | 4/09 – annual review; updated alt. |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/01/11 – annual review |
| Revised: | 3/01/12 – annual review, updated signature |
| Revised: | 3/01/13 – annual review, updated logo and definitions |
| Reviewed: | 3/01/14 – annual review |
| Revised: | 12/01/14 – updated policy to apply to all Lilly Insulin, updated signature |
| Revised: | 3/01/15 – annual review, removed vialed from Policy section 1, updated formatting |
| Reviewed: | 3/01/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting of dilution criteria |
| Revised: | 7/20/18 – added Fiasp exclusion to criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 99.0**

**SECTION: Commercial Drug**
**SUBJECT: Gefitinib**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for gefitinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of gefitinib may be made for members who meet the following criteria:

- Medical record documentation that gefitinib is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation of one of the following EGFR mutations as detected by an FDA approved test
    - Exon 19 deletion
    - Exon 21 (L858R) substitution

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Gefitinib is configured as a prior authorization for new starts only. Gefitinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved gefitinib will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Gilotrif*, erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/03 |
| Effective: | 10/03 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title |
| Revised: | 7/05 – updated criteria #3 |
| Revised: | 3/06 – updated title |

| Geisinger | POLICY NUMBER: 99.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Gefitinib |

Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Retired: 2012
Revised: 11/25/15 – policy reinstated, updated logo, removed failure of platinum/docetaxel, added EGFR requirements, added auth duration, QL, FA, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, indicated PA required for Tarceva
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated format of prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Tarceva to generic
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 11/1/23 – updated signature title; updated Iressa to gefitinib
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 104.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Somavert**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Somavert for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Somavert may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Somavert is prescribed by an endocrinologist **AND**
- Medical record documentation of a diagnosis of acromegaly **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of failure, intolerance to or contraindication with somatostatin analogs (octreotide or octreotide LAR)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Somavert will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

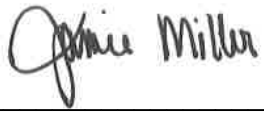
**FORMULARY ALTERNATIVES:**

bromocriptine, octreotide

| Geisinger | **POLICY NUMBER: 104.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Somavert** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/03 |
| Effective: | 10/03 |
| Reviewed: | 3/04 |
| Revised: | 2/05 – updated title |
| Reviewed: | 3/05 |
| Revised: | 3/0 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Revised: | 4/09 – annual review, updated alt |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/2/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated formatting |
| Revised: | 3/1/18 – annual review, updated signature, updated format of prescriber/age criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 105.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Teriparatide**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for teriparatide for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of teriparatide may be made for members who meet the following criteria:

- No medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- **For women:**
  - Medical record documentation of a diagnosis of osteoporosis **AND**
  - Medical record documentation of postmenopausal status or glucocorticoid induced osteoporosis **AND**
  - Medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years **AND**
  - Medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
  - Medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score –2.5 or below with documented risk factors)

**OR**

- **For men:**
  - Medical record documentation of a diagnosis of osteoporosis **AND**
  - Medical record documentation of an attempt of therapy with or contraindication to bisphosphonate therapy **OR**
  - Medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score less than -2.5)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- Forteo QL FOR LETTER ONLY: 2.4 mL per 28 days
- Teriparatide QL FOR LETTER ONLY: 2.48 per 28 days

**AUTHORIZATION DURATION**: Approval will be for 2 years, or less if there is medical record documentation of a previous incomplete course of therapy with a parathyroid hormone analog. Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

**NOTE:** Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

**Risk Factors Included in the WHO Fracture Risk Assessment Model**

- Current age
- Gender
- A prior osteoporotic fracture (including morphometric vertebral fracture)
- Femoral neck BMD
- Low body mass index (kg/m2)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)
- Oral glucocorticoids ≥5 mg/d of prednisone for ≥3 mo (ever)

From: WHO Technical Report.8

If an exception is made, teriparatide will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

alendronate, ibandronate, risedronate, Tymlos*

*prior authorization required

Geisinger

**POLICY NUMBER: 105.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Teriparatide**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/03 |
| Effective: | 10/03 |
| Reviewed: | 3/04 |
| Revised: | 2/05 – updated title |
| Reviewed: | 3/05 |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review-updated alts. |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo & definitions, updated alternatives, removed typo |
| Revised: | 3/1/14 – annual review, updated formatting, corrected typo |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated policy formatting, changed Actonel to risedronate |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/27/17 – removed prescriber, updated T-scores, bisphosphonate OR high risk |
| Revised: | 6/2/17 – added glucocorticoid inducing osteoporosis |
| Revised: | 9/28/17 – added no prior PTH, added QL/ risk factors, updated auth duration/note |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Forteo to generic |
| Revised: | 8/24/21 – added separate QL for teriparatide, corrected DS on Forteo QL |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, added generic only |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 110.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Gelclair**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gelclair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Gelclair may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of oral mucositis secondary to chemotherapy or radiation

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Gelclair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

sucralfate tablets
Maalox + viscous lidocaine + (otc) Benadryl liquid = Magic Mouthwash Compound

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

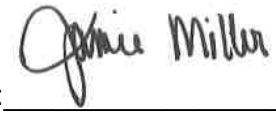
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 110.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Gelclair**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/04 |
| Effective: | 1/04 |
| Reviewed: | 3/04 |
| Revised: | 3/05 – updated title and formulary alts. |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Revised: | 4/09 – updated criteria |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 112.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Epsolay, Finacea Foam, and Zilxi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epsolay, Finacea foam, and Zilxi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Epsolay, Finacea foam, or Zilxi may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of rosacea with inflammatory lesions **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 for Epsolay, GPI-12 for Finacea foam or Zilxi.

If a formulary exception is approved, Epsolay, Finacea foam, or Zilxi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

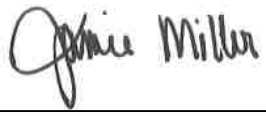
**FORMULARY ALTERNATIVES:**

metronidazole (cream/gel/lotion), ivermectin 1% cream, azelaic acid gel

| Geisinger | POLICY NUMBER: 112.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Epsolay, Finacea Foam, and Zilxi |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 04/04 |
| Effective: | 04/04 |
| Revised: | 3/05 – updated title |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Finacea gel to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/5/22 – added Epsolay & Zilxi; updated diagnosis criterion & number of alts. Required |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; added Zilxi to MediSpan authorization level |

Geisinger

**POLICY NUMBER: 118.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Modafinil**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for modafinil for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of modafinil may be made for members who meet **ONE** of the following criteria:

- Medical record documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome requiring treatment with nasal CPAP **OR**
- Medical record documentation of a diagnosis of narcolepsy **OR**
- Medical record documentation of a diagnosis of shift-work disorder **OR**
- Medical record documentation of fatigue associated with a diagnosis of multiple sclerosis **OR**
- Medical record documentation of a diagnosis of idiopathic hypersomnia

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, modafinil will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

Geisinger

**POLICY NUMBER: 118.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Modafinil**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/04 |
| Effective: | 10/04 |
| Reviewed: | 3/05 |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Revised: | 4/09 – annual review, updated alt. |
| Revised: | 1/10 – removed failure on stimulant for narcolepsy, removed formulary alt. |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 6/5/12 – added generic modafinil to policy |
| Revised: | 3/1/13 – annual review, updated logo & definitions, removed brand Provigil from policy |
| Revised: | 11/15/13 – added shift-work disorder & fatigue assoc. with multiple sclerosis indications |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 1/21/22 – added idiopathic hypersomnia to approved indications |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 120.0**

**SECTION: Commercial Drug**
**SUBJECT: Ezetimibe/Simvastatin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ezetimibe/simvastatin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of ezetimibe/simvastatin may be made for members who meet the following criteria:

- A diagnosis of primary hypercholesterolemia, mixed hyperlipidemia, or homozygous familial hypercholesterolemia with failure to meet goal LDL (per NCEP guidelines) goals on a combination of ezetimibe and simvastatin

**OR**

An exception for coverage of high dose ezetimibe/simvastatin (greater than 80 mg of simvastatin) may be made for members who meet the following criteria:

- Medical record documentation that the member has been utilizing simvastatin 80 mg for greater than 12 months **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, ezetimibe/simvastatin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 120.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ezetimibe/Simvastatin |

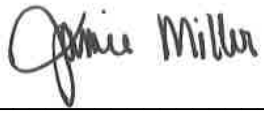
**FORMULARY ALTERNATIVES:**

atorvastatin, lovastatin, simvastatin, pravastatin, rosuvastatin, ezetimibe

For high dose ezetimibe/simvastatin: atorvastatin, rosuvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/05 |
| Revised: | 3/06 – updated title |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Revised: | 3/08 – annual review; updated alternatives |
| Revised: | 7/08 – removed failure on Lipitor/Crestor monotherapy from criteria |
| Revised: | 4/09 – annual review |
| Revised: | 3/10 – annual review, updated alt |
| Revised: | 3/1/11 – annual review-updated alts. |
| Revised | 9/11 – added criteria for high dose simvastatin |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 8/21/12 – changed Lipitor to atorvastatin |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo, updated alternatives |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, update policy formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – updated Crestor to rosuvastatin |
| Revised: | 3/1/17 – annual review, updated Zetia to ezetimibe |
| Revised: | 3/1/18 – annual review, updated signature, updated Vytorin to ezetimibe/simvastatin |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 120.0**

**SECTION: Commercial Drug**
**SUBJECT: Ezetimibe/Simvastatin**

Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 121.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alomide, Bepotastine, Lastacaft, Pazeo, & Zerviate**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alomide, bepotastine, Lastacaft, Pazeo, and Zerviate for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Alomide, bepotastine, Lastacaft, Pazeo, or Zerviate may be made for members who meet the following criteria:

- Medical record documentation of allergic conjunctivitis **AND**
- Medical record documentation of failure on, intolerance to or contraindication to azelastine eye drops, epinastine eye drops, olopatadine eye drops (generic Pataday or Patanol) **AND** OTC Zaditor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**ZERVIATE QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 units per day

If an exception is made Alomide, bepotastine, Lastacaft, or Pazeo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

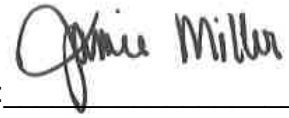
**FORMULARY ALTERNATIVES:**

azelastine eye drops (generic Optivar), epinastine (generic Elestat), olopatadine (generic Pataday or Patanol)

| Geisinger | POLICY NUMBER: 121.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Alomide, Bepotastine, Lastacaft, Pazeo, & Zerviate |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/05 |
| Revised: | 6/05 added Emadine |
| Revised: | 3/06 – updated title |
| Revised: | 3/07 – deleted ketotifen from formulary alternatives (now OTC) |
| Revised: | 5/07 – added signature |
| Revised: | 1/08 – added Optivar and Pataday, changed criteria |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review; updated criteria and alts. to reflect generics |
| Revised: | 9/11 – added Lastacaft, removed epinastine (now generic), updated alternatives |
| Revised: | 3/1/12 – annual review, updated signature, logo, fixed typo, updated alternatives |
| Revised: | 3/1/13 – annual review, updated logo, definitions, and signature |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – removed Patanol from policy since no PA required, added olopatadine to FA |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 11/27/17 – added Bepreve & Pazeo, updated criteria to failure to include epinastine, olopatadine (generic Pataday/Patanol), removed brand Pataday, updated FA, updated signature |
| Reviewed: | 3/1/18 – annual review |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/20/23 – added Zerviate |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated bepotastine to generic and removed Emadine (discontinued) |

Geisinger

**POLICY NUMBER: 124.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lenalidomide**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lenalidomide for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of lenalidomide may be made for members who meet the following criteria:

<u>For Myelodysplastic Syndromes (MDS)</u>

- Medical record documentation that lenalidomide is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the treatment of a patient with myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities

**OR**

With no deletion 5q cytogenetic abnormality:

- Medical record documentation of initial use in lower risk patient with symptomatic anemia and serum erythropoietin levels greater than 500 mU/mL and a low probability of response to immunosuppressive therapy* **OR**
- Medical record documentation of lower risk patient with symptomatic anemia and no response to initial treatment with epoetin alfa or darbepoetin alfa, hypomethylating agents, or immunosuppressive therapy

*Low probability is defined as members who lack any of the following features: age less than or equal to 60, those with hypocellular marrows, HLA-DR15 or PNH clone positivity

**OR**

For Multiple Myeloma

- Medical record documentation that lenalidomide is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma

**OR**

For Non-Hodgkin Lymphomas (NHL)

- Medical record documentation that lenalidomide is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of NHL (relapsed, refractory, progressive disease, or members who are not candidates for high dose therapy)

**OR**

For Mantle Cell Lymphoma

- Medical record documentation that lenalidomide is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed, refractory, or progressive mantle cell lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy

**OR**

For Follicular Lymphoma

- Medical record documentation that lenalidomide is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of follicular lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation that Revlimid is being used in combination with a rituximab product

**OR**

For Marginal Zone Lymphoma

- Medical record documentation that lenalidomide is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of marginal zone lymphoma **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation that lenalidomide is being used in combination with a rituximab product

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 2.5 mg, 5 mg, & 10 mg capsules: 1 capsule per day, 28 day supply per fill
  - 15 mg, 20 mg, & 25 mg capsules: 21 capsules per 28 days

**RE-AUTHORIZATION CRITERIA:** Lenalidomide is configured as a prior authorization for new starts only. Lenalidomide will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, lenalidomide will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

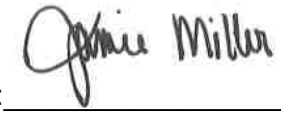
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 124.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lenalidomide** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/06
Reviewed: 3/07
Revised: 5/07 – added multiple myeloma indication; added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 7/18/12 – added non-Hodgkin Lymphoma indication, altered myelodysplastic syndrome & multiple myeloma indications to match NCCN recommendation
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 10/7/13 – added mantle cell lymphoma indication
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 6/2/17 – added QL
Revised: 10/10/17 – added authorization duration
Revised: 3/1/18 – annual review, updated signature, added grandfather and approval language
Revised: 6/1/18 – updated QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 7/23/19 – added follicular lymphoma and marginal zone lymphoma indications
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 8/4/20 – corrected typo
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, added prescriber criteria to each indication
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review, update Revlimid to lenalidomide
Revised: 3/1/24 – annual review; updated signature title; updated Revlimid to lenalidomide in criteria

Geisinger

**POLICY NUMBER: 125.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sprycel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sprycel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Sprycel may be made for members who meet the following criteria:

- Medical record documentation that Sprycel is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the use of Sprycel to treat newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) **OR**
- Medical record documentation of the use of Sprycel to treat chronic, accelerated, or myeloid/lymphoid blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib **OR**
- Medical record documentation of use of Sprycel to treat Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy **OR**
- Medical record documentation of use of Sprycel to treat newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) in pediatric patients 1 year and older in combination with chemotherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 20 mg tablet: 3 tablets per day, 30 day supply per fill
  - 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Sprycel is configured as a prior authorization for new starts only. Sprycel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made Sprycel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Chronic, Accelerated, or Myeloid/Lymphoid Blast Phase Ph+ CML: imatinib

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 125.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sprycel**

| | |
|---|---|
| Devised: | 10/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 12/10 – added criteria to support new FDA approved indication |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, corrected typo, updated formatting, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – removed copay per 15 day supply requirement |
| Revised: | 5/1/16 – updated format, logo, & procedure, updated note to authorization duration |
| Revised: | 3/1/17 – annual review, updated Gleevec to imatinib |
| Revised: | 8/8/17 – updated FA, added newly diagnosis to chronic phase CML, clarified criteria for Ph+ CML |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/18 – updated prescriber criteria, added Ph+ to newly diagnoses CML, defined abbreviations, updated signature |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/28/19 – added pediatric ALL indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 127.0**

**SECTION: Commercial Drug**
**SUBJECT: Fenofibrate Micronized (generic Antara)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for fenofibrate micronized (generic Antara) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of fenofibrate micronized (generic Antara) may be made for members who meet all the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to gemfibrozil **AND** fenofibrate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, fenofibrate micronized (generic Antara) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

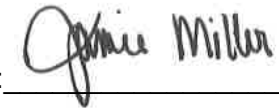
**FORMULARY ALTERNATIVES:**

gemfibrozil, fenofibrate, cholestyramine, colestipol, atorvastatin, lovastatin, simvastatin, pravastatin, rosuvastatin, ezetimibe, niacin ER, omega-3 fatty acids (generic Lovaza)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 127.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Fenofibrate Micronized (generic Antara)** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Revised: | 3/08 – annual review; updated alternatives |
| Revised: | 4/09 – annual review, removed Tricor from title, updated alt. |
| Revised: | 3/10 – annual review, updated alt. |
| Reviewed: | 3/1/11 – annual review-updated alts |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, removed Lofibra from policy based on generic availability, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature, changed Niaspan to generic Niacin ER |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – updated Crestor to rosuvastatin |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated to generic only |

Geisinger

**POLICY NUMBER: 129.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Apidra**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Apidra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Apidra may be made for members who meet all the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Novolog

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

If an exception is made, Apidra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

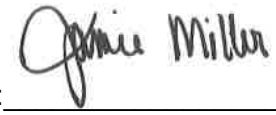
**FORMULARY ALTERNATIVES:**

Novolog, insulin aspart

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 129.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Apidra** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, corrected typo |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 130.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Symlin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symlin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Symlin may be made for members who meet all the following criteria:

- Medical record documentation of Symlin being used as an adjunct treatment in patients who use mealtime insulin therapy **AND**
- Medical record documentation of failure to achieve desired glucose control despite optimal insulin therapy, which may be with or without a concurrent sulfonylurea agent and/or metformin for those with Type 2 diabetes

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Symlin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

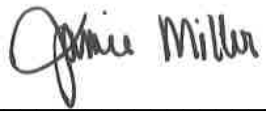
**FORMULARY ALTERNATIVES:**

Lantus, Toujeo, Levemir, Tresiba, Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 70/30, insulin aspart, insulin aspart protamine/insulin aspart 70/30

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 130.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Symlin** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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|---|---|
| Devised: | 10/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added Toujeo to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 131.0**

**SECTION: Commercial Drug**
**SUBJECT: Byetta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Byetta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Byetta may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 5 mcg Pen: 0.04 mL per day
  - 10 mcg Pen: 0.08 mL per day

If an exception is made, Byetta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 131.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Byetta |

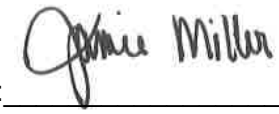
**FORMULARY ALTERNATIVES:**

Ozempic*, Victoza*, Rybelsus*, Trulicity*, Mounjaro*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Revised: | 3/08 – annual review; updated alternatives |
| Revised: | 4/09 – annual review, updated alt. |
| Reviewed: | 3/10 – annual review |
| Revised: | 8/10 – updated criteria |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 6/21/12 – added Bydureon to policy |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 1/2/14 – added failure of Victoza to Byetta criteria, updated formulary alternatives |
| Revised: | 3/1/14 – annual review, updated alternatives based on generic availability of Prandin, added approval statement |
| Revised: | 1/13/15 – removed Bydureon from policy, updated FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, added Toujeo, Jardiance, Synjardy, Invokana, & Invokamet to FA, updated PA/ST language |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/27/17 – failure of Tanzeum, added QL |
| Revised: | 6/2/17 – removed failure of other antidiabetic |
| Revised: | 1/17/18 – updated failure from Tanzeum to Ozempic, updated QL to add both authorizations, updated FA, updated signature |
| Revised: | 3/1/18 – annual review, updated FA |

Revised: 3/1/19 – annual review, updated QL approval note & FA, removed step indicator from alts.
Revised: 1/28/20 – added failure of Rybelsus and updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review; updated logo, FA, & QL statement; added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Revised: 3/1/23 – annual review, updated FA
Revised: 3/1/24 – annual review; updated signature title; updated FA

| Geisinger | POLICY NUMBER: 132.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Sorafenib |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sorafenib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and

E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of sorafenib may be made for members who meet all the following criteria:

- Medical record documentation of the use of sorafenib for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation that sorafenib is prescribed by an oncologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Sorafenib is configured as a prior authorization for new starts only. Sorafenib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, sorafenib will be paid for under the member's prescription drug benefit.

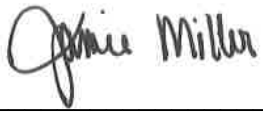
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 132.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Sorafenib |

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, corrected typo, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – removed copay per 15 day supply requirement |
| Revised: | 5/1/16 – updated format, logo, & procedure, changed note to authorization duration |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months. |
| Revised: | 3/1/18 – annual review, updated signature & format, added grandfather language |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 11/1/23 – updated signature title; updated Nexavar to sorafenib |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 133.0**

**SECTION: Commercial Drug**
**SUBJECT: Sunitinib**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sunitinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of sunitinib may be made for members who meet all the following criteria:

**Gastrointestinal Stromal Tumor (GIST)**

- Medical record documentation that sunitinib is prescribed by an oncologist **OR** gastroenterologist **AND**
- Medical record documentation of a diagnosis of gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to imatinib (Gleevec)

**Pancreatic Neuroendocrine Tumors (pNET)**

- Medical record documentation that sunitinib is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in a member with unresectable locally advanced or metastatic disease

**Advanced Renal Cell Carcinoma (RCC)**

- Medical record documentation that sunitinib is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma

**Renal Cell Carcinoma, adjuvant treatment**

- Medical record documentation that sunitinib is prescribed by an oncologist **AND**
- Medical record documentation that member is an adult at high risk** of recurrent renal cell carcinoma following nephrectomy

****NOTE:** In clinical trials, high risk disease was defined as a score of greater than or equal to T3 on the University of California Los Angeles Integrated Staging System and/or node positive tumors.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Sunitinib is configured as a prior authorization for new starts only. Sunitinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, sunitinib will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

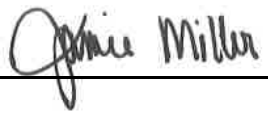
**FORMULARY ALTERNATIVES:**

Gleevec for treatment of GIST

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 133.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Sunitinib** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 8/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typo, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed copay per 15 day supply requirement, updated note
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/18 – updated policy to include description of FDA indications, updated FA, added note, added QL, updated signature
Revised: 3/1/18 – annual review, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated Sutent to generic, added generic only approval
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 135.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ranolazine ER**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ranolazine ER for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of ranolazine ER may be made for members who meet all the following criteria:

- Medical record documentation of use for the treatment of chronic angina not adequately responding to other antianginal drugs **AND**
- Medical record documentation of use with combination of amlodipine, beta-blockers, or nitrates **AND**
- No medical record documentation of concurrent use of potent/moderately potent CYP3A4 inhibitors (diltiazem, verapamil, azoles, macrolides, etc.) or QT prolonging medications **AND**
- Medical record documentation that ranolazine ER is prescribed by a cardiologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, ranolazine ER will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Beta-blockers: acebutolol, atenolol, InnoPran XL, metoprolol, nadolol, propranolol, metoprolol XL
Calcium channel blockers: felodipine, nifedipine, nifedipine SR, amlodipine, isradipine, nimodipine
Nitrates: isosorbide dinitrate, isosorbide mononitrate, nitroglycerin

| Geisinger | POLICY NUMBER: 135.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ranolazine ER |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/07 |
| Revised: | 3/07-typo fixed, updated formulary alternatives |
| Revised: | 5/07 – added signature |
| Revised: | 3/08 – annual review; updated alternatives |
| Revised: | 4/09 – annual review, updated alt. |
| Reviewed: | 3/10 – annual review |
| Revised: | 5/10 – updated form alt. removed diltiazem and verapamil |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated format of prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Ranexa to generic ranolazine ER |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 139.0**

**SECTION: Commercial Drug**
**SUBJECT: Miglustat**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for miglustat for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of miglustat may be made for members who meet the following criteria:

- Medical record documentation of miglustat being used to treat an adult patient with mild to moderate Type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (for example, due to constraints such as allergy, hypersensitivity, or poor venous access) **AND**
- Miglustat is recommended by a metabolic specialist with experience in treating Gaucher disease

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 capsules per day, 30 day supply per fill

If an exception is made, miglustat will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

None for pharmacy. Cerezyme and Elelyso require prior authorization under the medical benefit.

Geisinger

**POLICY NUMBER: 139.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Miglustat**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/06 |
| Reviewed: | 3/07 |
| Revised: | 5/07 – added signature |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 –annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review-updated criteria to add metabolic specialist |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, updated formatting, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Zavesca to generic miglustat |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review defined e.g. |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 140.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Quinine Sulfate**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for quinine sulfate for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of quinine sulfate may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of malaria or babesiosis

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, quinine sulfate will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

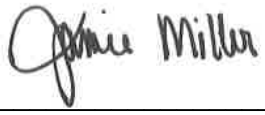
**FORMULARY ALTERNATIVES:**
hydroxychloroquine, pyrimethamine*, chloroquine, mefloquine

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 140.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Quinine Sulfate** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/07 |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, added approval statement, updated alternatives based on availability of generic Lariam |
| Revised: | 3/1/15 – annual review, updated signature, changed Qualaquin to quinine sulfate, removed Fansidar from alternatives |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, updated Qualaquin to quinine sulfate |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated to GPI-12 |

Geisinger

**POLICY NUMBER: 141.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Januvia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Januvia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Januvia may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Januvia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

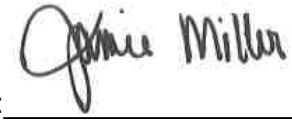
**FORMULARY ALTERNATIVES:**

metformin, Tradjenta, Jentadueto, Jentadueto XR

| Geisinger | **POLICY NUMBER: 141.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Januvia** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/07 |
| Revised: | 6/07 – Removed criterion 3 (concomitant use with sulfonylurea/insulin) |
| Reviewed: | 3/08 – annual review |
| Revised: | 4/09 – annual review, updated alt. |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review-updated alts. |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 11/28/17 – updated to failure of metformin, updated FA, updated signature, added ST language, added QL, added new starts vs. existing failure of Tradjenta |
| Revised: | 2/2/18 – removed old criteria requiring step through metformin |
| Revised: | 3/1/18 – annual review, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note, removed step indicator from alts. |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 142.0**

**SECTION: Commercial Drug**
**SUBJECT: Posaconazole Suspension/Tablets & Noxafil PowderMix Packets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for posaconazole suspension/tablets and Noxafil PowderMix packets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of posaconazole may be made for members who meet the following criteria:

**Prophylaxis of Invasive Aspergillus or Candida Infections**

- Medical record documentation that posaconazole is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation of one of the following:
    - If request is for Noxafil oral suspension: medical record documentation of age greater than or equal to 13 years **OR**
    - If request is for posaconazole delayed release tablets: medical record documentation of age greater than or equal to 2 years and documentation of weight greater than 40 kilograms
    - If request is for Noxafil PowderMix packets: medical record documentation of age greater than or equal to 2 years and less than 13 years **AND** documentation of weight greater than or equal to 10 kilograms to less than 40 kilograms

**Treatment of Invasive Aspergillosis**

- Medical record documentation that posaconazole is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for treatment of invasive aspergillosis **AND**
- Medical record documentation of age greater than or equal to 13 years

**Treatment of Oropharyngeal Candidiasis**

- Medical record documentation that posaconazole is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of treatment of oropharyngeal candidiasis with therapeutic failure on, contraindication to, or intolerance to fluconazole or itraconazole*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, if request is for tablets or suspension add generic only

**QUANTITY LIMIT:**

- **100 mg tablets –**
    - Initial approval: Two authorizations must be entered.
        1. In PA Hub: Add ST, PA, and PE. Start date of this authorization is one-day after loading dose ends.
        2. In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims authorized, and max quantity dispensed 93 per 28 days with a duration of one-week.
    - Renewal: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
    - INITIAL QL FOR LETTER: Loading dose: 93 tablets per 30 days; Maintenance dose: 90 tablets per 30 days
    - RENEWAL QL FOR LETTER: 90 tablets per 30 days
- **200 mg/5 mL suspension –** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
    - QL FOR LETTER: 20 mL per day
- **PowderMix Packets –**
    - Initial approval: Two authorizations must be entered.
        1. In PA Hub: Add PA. Start date of this authorization is one-day after loading dose ends.
        2. In Darwin: Add PA, OQL, enter 1 in max number of claims authorized, and max quantity dispensed 31 per 30 days with a duration of one-week.
    - Renewal: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
    - INITIAL QL FOR LETTER: Loading dose: 31 packets per 30 days; Maintenance dose: 30 packets per 30 days
    - RENEWAL QL FOR LETTER: 30 packets per 30 days

**AUTHORIZATION DURATION:**

- **For prophylaxis of invasive aspergillus and candida infections:** Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member recovers from neutropenia and/or immunosuppression.
- **For treatment of invasive aspergillus and candida infections:** 3 months or less if the reviewing provider feels it is medically appropriate
- **For oropharyngeal candidiasis:** One-time, 28 days authorization

If an exception is made, posaconazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

fluconazole, itraconazole*, voriconazole*

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/07

| | |
|---|---|
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, added approval statement |
| Revised: | 3/1/15 – annual review, update signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated formatting |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 5/29/19 – added auth duration and QL |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Noxafil to generic |
| Revised: | 11/24/21 – separated indications, updated age requirements for prophylaxis, added treatment of aspergillus, updated generic only to only tablets |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 7/25/23 – added Noxafil PowderMix packets; updated signature title |
| Revised: | 3/1/24 – annual review; updated suspension to generic only entry |

Geisinger

**POLICY NUMBER: 147.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Epogen, Procrit, Aranesp, and Retacrit**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epogen, Procrit, Aranesp, and Retacrit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Epogen, Procrit, Aranesp, or Retacrit may be made for members for the following indications when reversible or correctable conditions including but not limited to, vitamin B12 deficiency, hemolysis, iron or folate deficiency and blood loss have been ruled out and when all of the indication specific criteria are met:

Medical record documentation of:

1. Treatment of symptomatic anemia of chronic renal insufficiency, chronic renal failure, including end stage renal disease either requiring or not requiring dialysis when all of the following criteria are met:
    - Hemoglobin less than or equal to 10 g/dL for new starts or less than 11 g/dL for continuation of therapy **OR** medical record documentation that the dose will be reduced or interrupted if hemoglobin exceeds 11g/d **AND**
    - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron

2. Treatment of symptomatic anemia in zidovudine-treated HIV infected insured individuals when all of the following criteria are met:
    - Endogenous erythropoietin levels of 500 MU/mL or less **AND**
    - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron **AND**
    - Zidovudine doses of 4200 mg or less per week **AND**
    - Hemoglobin less than 12 g/dL for continuation therapy or less than 10 g/dL for new starts

    Treatment should not last longer than 3 months following the discontinuation of zidovudine.

3. Treatment of anemia secondary to myelosuppressive chemotherapy in non-myeloid malignancies when all of the following criteria are met:
    - Hemoglobin less than or equal to 12 g/dL for continuation therapy or less than 10 g/dL for new starts **AND**
    - Insured individual is currently on anemia-inducing chemotherapy and there is a minimum of two additional months of planned chemotherapy **AND**
    - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron

    Non-myeloid malignancies include all types of carcinoma, sarcoma, melanoma, multiple myeloma, lymphoma, and lymphocytic leukemia.

4. Treatment of symptomatic anemia secondary to myelodysplastic syndrome (MDS) when all of the following criteria are met:
    - Hemoglobin less than or equal to 12 g/dL for continuation therapy or less than 10 g/dL for new starts **AND**
    - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron **AND**
    - Baseline endogenous erythropoietin levels of 500 MU/mL or less (NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes v2.2010)

5. Treatment of symptomatic anemia of chronic disease (rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus, and hepatitis C undergoing treatment) when all of the following criteria are met:
    - Hemoglobin less than 12 g/dL for continuation therapy or less than 10 g/dL for new starts **AND**
    - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron **AND**
    - Insured individual has a severe comorbidity (e.g. severe angina, pulmonary disease, heart failure, cerebrovascular disease causing transient ischemic attacks, lymphoma, myeloma, etc.) **AND**
    - Insured individual's anemia is manifested by impairments such as, but not limited to, exercise intolerance, tachycardia or shortness of breath with minimal activity, or inability to perform activities of daily living

6. Reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery when all of the following criteria are met:
    - Hemoglobin less than 13 g/dL **AND**
    - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron **AND**
    - Anemia is related to chronic disease state (limited to rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus, and hepatitis C undergoing treatment) **AND**
    - Insured individual is scheduled to undergo elective, non-cardiac, non-vascular surgery in which anticipated blood loss is greater than 2 units and the need for allogeneic blood transfusion is anticipated.

    Authorization will be for a duration of 1 month. Request for use beyond 4 weeks will require medical record documentation indicating medical necessity.

    **Note:** Erythropoietin therapy (epoetin alfa) is not indicated for anemic patients who are able and willing to donate autologous blood.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

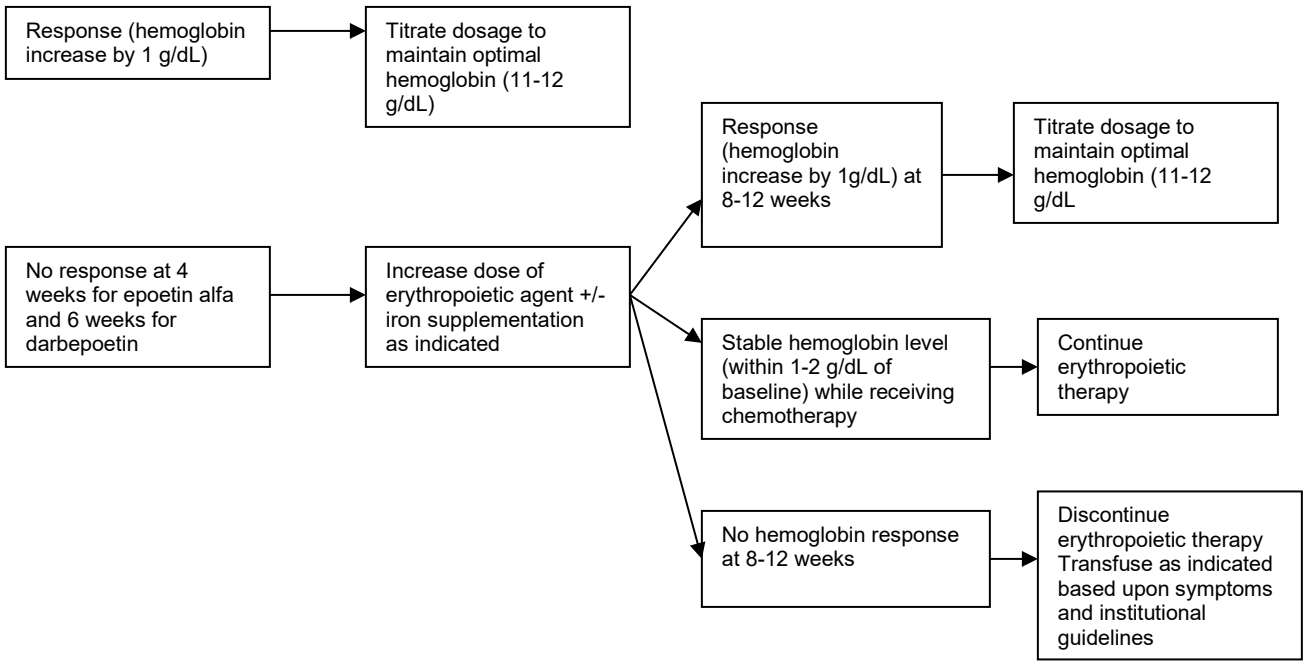
**AUTHORIZATION DURATION:**
Except for the indication for use in anemic surgical patients, approval for Epogen, Procrit, Aranesp, or Retacrit therapy will be given for an initial duration of 12 months. Subsequent authorization will be considered based on the stated criteria.

**GENERAL GUIDANCE:**

- For continuation of therapy, a repeat Hgb should be submitted after 12 months of therapy.
- In individuals whose Hgb is greater than or equal to 12g/dL or rises by 1g/dL in any two-week period, additional doses should be withheld. (In insured individuals with Hgb of greater than or equal to 12 g/dL Erythropoietin or Darbepoetin therapy will not be covered according to FDA recommendations, except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

**LIMITATIONS:**
**For treatment of anemia in MDS and non-myeloid cancer (on chemotherapy)**:

**Initial Response Assessment**
**Subsequent response Assessment**




**Adapted from NCCN, Clinical Practice Guidelines in Oncology, v3, 2007**

An initial response assessment distinguishes individuals with a response (Hgb increase by 1 g/dL) from those with no response to erythropoietic therapy. In individuals with a response, erythropoietin should be continued to maintain an optimal hemoglobin (12 g/dL). Assessment of individuals with no response to therapy should be performed at 4 weeks for epoetin alfa and 6 weeks for darbepoetin. If no response is detected, a dose increase of the erythropoietic agent is recommended with or without iron supplementation as indicated. If the hemoglobin level increases by 1 g/dL at 8-12 weeks of erythropoietic therapy then a dosage titration should be performed to maintain an optimal hemoglobin level at 12 g/dL. Erythropoietic therapy should be discontinued and transfusion initiated as indicated if there is no hemoglobin response at 8-12 weeks of therapy.

**EXCLUSIONS:**
Erythropoietin and Darbepoetin therapy is not covered for the following conditions because current clinical data indicates that erythropoietin stimulating agents have been shown to impart either a deleterious effect on the underlying disease, or that the underlying disease increases the risk of adverse effects related to use of erythropoietin stimulating agents. These conditions include but are not limited to:

- Anemia of cancer not related to cancer treatment;
- Anemia related to myelosuppressive chemotherapy when the cancer treatment goal is cure (e.g. early stage breast cancer, Hodgkin lymphoma, non-Hodgkin's lymphoma, testicular cancer, Early stage non-small cell lung cancer, small cell lung cancer)
- Anemia associated only with radiotherapy;
- Anemia due to cancer treatment in insured individuals with uncontrolled hypertension;
- Anemia associated with the treatment of acute and/or chronic myelogenous leukemias (CML or AML), or erythroid cancers;
- Anemia in cancer or in cancer treatment due to folate deficiency, iron deficiency, vitamin B-12 deficiency, bleeding, hemolysis, or bone marrow fibrosis;
- Prophylactic use of erythropoietin stimulating agents to prevent chemotherapy-induced anemia;
- Prophylactic use of erythropoietin stimulating agents to reduce tumor hypoxia;
- Erythropoietin-type resistance due to neutralizing antibodies

If an exception is made, Epogen, Procrit, Aranesp, or Retacrit will be paid for under the member's prescription drug benefit.

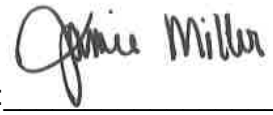
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 147.0 |
|---|---|
| POLICY AND PROCEDURE<br>PHARMACY<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Epogen, Procrit, Aranesp, and Retacrit |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/07 |
| Reviewed: | 3/08 – annual review |
| Revised: | 7/08 – updated criteria |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typos |
| Revised: | 3/1/14 – annual review, fixed two typos |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 3/1/16 – annual review, updated policy formatting |
| Revised: | 3/24/16 – updated Hgb requirement for CKD (11 & 12 to 10 & 11), zidovudine-treated HIV (11 to 10), myelosuppressive chemo (11 to 10), MDS (11 to 10), chronic disease (11 to 10); updated myelosuppressive chemo heading; updated chemo requirement for myelosuppressive chemo; added list of non-myeloid malignancies; removed Hep C chemo; added list of chronic diseases; removed Hgb > 10 for allogeneic blood transfusion; added auth duration to allogeneic blood transfusion; removed MM requirements; removed original auth duration & added new language; added general guidance; updated exclusion section |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/8/16 – updated Hgb requir. under general guidance, corrected typos under exclusions |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 11/26/18 – added Retacrit, added “or history of chelation therapy for iron,” defined abbreviations, added hep C to section 5, added listing of chronic diseases to section 6 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 148.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Paliperidone Extended Release**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for paliperidone extended release for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of paliperidone extended release may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to risperidone, olanzapine, quetiapine, **AND** aripiprazole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, paliperidone extended release will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

risperidone, olanzapine, quetiapine fumarate, aripiprazole

| Geisinger | POLICY NUMBER: 148.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Paliperidone Extended Release |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/07 |
| Reviewed: | 3/08 – annual review |
| Revised: | 4/09 – annual review, updated alt. |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated policy formatting, changed Abilify to aripiprazole |
| Revised: | 5/1/16 – updated format, logo, & procedure, changed Seroquel to quetiapine |
| Revised: | 3/1/17 – annual review, updated Invega to paliperidone extended release |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 151.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Verdeso**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verdeso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Verdeso may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to formulary low-potency topical steroids

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Verdeso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

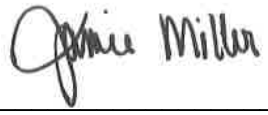
**FORMULARY ALTERNATIVES:**

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 151.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Verdeso** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/07 |
| Reviewed: | 3/08 – Annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo & definitions |
| Revised: | 3/1/14 – annual review, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 3/1/16 – annual review, removed extra roman numeral from FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 152.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zolinza**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zolinza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zolinza may be made for members who meet the following criteria:

- Medical record documentation of use of Zolinza to treat cutaneous manifestations in patients with cutaneous T-cell lymphoma **AND**
- Medical record documentation of resistance or intolerance to two prior therapies **AND**
- Medical record documentation that Zolinza is prescribed by a hematologist or oncologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**RE-AUTHORIZATION CRITERIA:** Zolinza is configured as a prior authorization for new starts only. Zolinza will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- 4 capsules per day, 30 day supply per fill

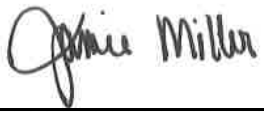
If an exception is made, Zolinza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/07 |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, added approval statement |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated policy formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – added authorization duration |
| Revised: | 3/1/18 – annual review, updated signature & format, added grandfather language |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |

Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 154.0**

**SECTION: Commercial Drug**
**SUBJECT: Aliskiren**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for aliskiren for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***ACE Inhibitor*** – angiotensin converting enzyme inhibitor
7. ***ARB*** – angiotensin receptor blocker

**PROCEDURE:**

An exception for coverage of aliskiren may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three classes of formulary blood pressure medications, one of which must be an angiotensin converting enzyme (ACE) inhibitor and one of which must be an angiotensin receptor blocker (ARB)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, aliskiren will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**ACE inhibitors:** benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, trandolapril, ramipril
**ACE inhibitors/Diuretics**: captopril/hctz, benazepril/hctz, enalapril/hctz, lisinopril/hctz, moexipril/hctz
**Alpha-Beta Blockers:** labetalol, carvedilol
**Antiadrenergic (Peripheral Acting):** prazosin, doxazosin, terazosin
**Antiadrenergic (Central Acting):** clonidine, methyldopa, guanfacine
**ARBs:** losartan, irbesartan, valsartan

**ARBs/Diuretics**: losartan/hctz, irbesartan/hctz, valsartan/hctz
**Beta Blockers:** acebutolol, pindolol, nadolol, atenolol, propranolol, metoprolol
**Beta Blockers/Diuretics**: bisoprolol/hctz
**Calcium Channel Blockers:** verapamil, nifedipine, diltiazem, felodipine, amlodipine, isradipine, nimodipine
**Calcium Channel Blockers/Ace Inhibitor**: amlodipine/benazepril
**Diuretics:** furosemide, hydrochlorothiazide, spironolactone, chlorthalidone, spironolactone/ hctz, triamterene/ hctz, bumetanide, metolazone, torsemide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/07 |
| Revised: | 3/08 – annual review; updated alternatives |
| Reviewed: | 4/09 – annual review, updated alt. |
| Revised: | 3/10 – added Valturna to policy |
| Revised: | 4/10 – updated alternatives |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature and alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, added valsartan/hctz to FA, corrected two typos, Valturna D/C by manufacturer and removed from policy |
| Revised: | 3/1/15 – annual review, updated signature, added irbesartan & irbesartan/hctz as FA |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, added ACE & ARB to definitions |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo, updated FA |
| Revised: | 3/1/19 – annual review, defined abbreviations |
| Revised: | 11/21/19 – updated Tekturna to generic Aliskiren |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 154.0**

**SECTION: Commercial Drug**
**SUBJECT: Aliskiren**

Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 158.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Altabax**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Altabax for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Altabax may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of impetigo **AND**
- Medical record documentation that member's age is greater than 9 months **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to mupirocin ointment **AND** oral antibiotic therapy

**AUTHORIZATION DURATION:** 5 days, RX count 1

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Altabax will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

mupirocin ointment, gentamicin cream and ointment, cephalexin, dicloxacillin, erythromycin, clarithromycin, clindamycin, sulfamethoxazole/trimethoprim, doxycycline

| Geisinger | POLICY NUMBER: 158.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Altabax |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/07 |
| Reviewed: | 3/08 – annual review |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated policy formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated FA to define appropriate oral abx |
| Revised: | 4/1/19 – added auth duration |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated patient to member |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 159.0**

**SECTION: Commercial Drug**
**SUBJECT: Amlodipine/valsartan and Amlodipine/valsartan/hctz**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for amlodipine/valsartan and amlodipine/valsartan/hctz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of amlodipine/valsartan or amlodipine/valsartan/hctz may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three preferred formulary angiotensin receptor blockers, one of which must be valsartan, used in combination with amlodipine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, amlodipine/valsartan or amlodipine/valsartan/hctz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**ARB component:** candesartan (generic Atacand), losartan (generic Cozaar), irbesartan (generic Avapro), olmesartan (generic Benicar), telmisartan (generic Micardis), valsartan (generic Diovan)
**ARBs/Diuretic component:** losartan/hctz (generic Hyzaar), valsartan/hctz (generic Diovan HCT), irbesartan/hctz (generic Avapro HCT) candesartan/hctz (generic Atacand HCT), olmesartan/hctz (generic Benicar HCT), telmisartan/hctz (generic Micardis HCT), valsartan (generic Diovan)
**Calcium Channel Blocker component:** amlodipine (generic Norvasc)

Geisinger

**POLICY NUMBER: 159.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Amlodipine/valsartan and Amlodipine/valsartan/hctz**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/08 |
| Revised: | 3/08 – annual review; updated alternatives |
| Revised: | 4/09 – annual review, updated alt. |
| Revised: | 11/09 – added Exforge HCT, updated alt. |
| Reviewed: | 3/10 – annual review |
| Revised: | 4/10 – updated alternatives |
| Revised: | 3/1/11 – annual review-clarified criteria and alternatives |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, updated FA to include valsartan/hctz |
| Revised: | 12/1/14 – added failure of irbesartan, updated FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 9/19/15 – added failure of valsartan, updated FA |
| Revised: | 3/1/16 – annual review, updated brand names to generic |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 5/29/19 – updated criteria to 3 preferred ARBs, updated FA, deleted note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 162.0**

**SECTION: Commercial Drug**
**SUBJECT: Filgrastim and Pegfilgrastim Injections**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Neupogen, Neulasta, Fulphila, Udenyca, Ziextenzo, Leukine, Zarxio, Granix, Nivestym, Releuko, Nyvepria, Fylnetra, Stimufend, and Rolvedon for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Neupogen, Neulasta, Fulphila, Udenyca, Ziextenzo, Leukine, Zarxio, Granix, Nivestym, Releuko, Nyvepria, Fylnetra, Stimufend, and Rolvedon may be made for members who meet the following criteria:

**NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, GRANIX, NIVESTYM, RELEUKO, NYVEPRIA, FYLNETRA, STIMUFEND, AND ROLVEDON**

- **Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:**

**Primary Prophylaxis** – For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria Fylnetra, Stimufend, **AND** Fulphila

**NOTE:** Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

**OR**

For the prevention of FN when the risk of developing FN is less than 20%, but **any** other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin greater than 2.0)
- Renal dysfunction (CrCl less than 50)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

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**NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, NIVESTYM, RELEUKO, NYVEPRIA, FYLNETRA, STIMUFEND, AND ROLVEDON**

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

**Secondary Prophylaxis** – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Treatment of Febrile Neutropenia** – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Dose Dense Therapy** – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Stem Cell Transplantation** – when one of the following is met:

- Bone marrow transplant (BMT) –
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

**OR**

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
  - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**NOTE: Neulasta, Udenyca, Ziextenzo, Nyvepria, Fylnetra, Stimufend, and Fulphila are considered off-label for PBPC mobilization. Rolvedon is not indicated for PBPC mobilization.**

**Leukemia or Myelodysplastic Syndromes** – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Lymphoma** – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Radiation therapy** –

- If prolonged delays secondary to neutropenia are anticipated
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

**NOTE: Fulphila, Ziextenzo, Nyvepria, Fylnetra, Stimufend, and Udenyca are considered off-label for radiation injury syndrome; however, the biosimilars are considered medically accepted for this use by the NCCN guidelines.**

**Rolvedon is not indicated for radiation injury syndrome.**

**ROLVEDON**

- Medical record documentation of age greater than or equal to 18 years

**NEUPOGEN, ZARXIO, NIVESTYM, and RELEUKO**

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

**Severe Chronic Neutropenia** – when the following criteria are met:

- Diagnosis of congenital, cyclic, or idiopathic neutropenia **AND**
- Documentation of an absolute neutrophil count (ANC) <500 cells/mm3 on three separate occasions during a 6 month period (for congenital or idiopathic neutropenia) **OR** five consecutive days of ANC <500 cells/mm3 per cycle (for cyclic neutropenia) **AND**
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months
- prolonged delays secondary to neutropenia are anticipated

**LEUKINE**

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

**Delayed Neutrophil Recovery or Graft Failure**

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/$mm^3$ or greater.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**AUTHORIZATION DURATION:** 6 months

**NEULASTA/FULPHILA/ZIEXTENZO/UDENYCA/NYVEPRIA/FYLNETRA/STIMUFEND/ ROLVEDON QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 syringe per 14 days (0.043 mL per day)

If an exception is made, Neupogen, Neulasta, Fulphila, Leukine, Udenyca, Ziextenzo, Zarxio, Granix, Nivestym, Releuko, Fylnetra, Stimufend, Rolvedon, or Nyvepria will be paid for under the member's prescription drug benefit.

**EXCLUSIONS:**
There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for "priming" effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

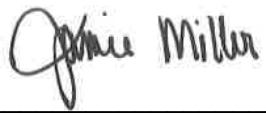
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

| Geisinger | POLICY NUMBER: 162.0 |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Filgrastim and Pegfilgrastim Injections** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typo
Revised: 12/1/14 – added Neulasta QL, updated signature
Reviewed: 3/1/15 – annual review
Revised: 11/20/15 – added Zarxio to policy
Revised: 12/26/15 – add: "uses supported by clinical guidelines" to policy
Revised: 3/1/16 – annual review, added Zarxio to approval statement
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 6/1/18 – updated TC regimen, added notes regarding 20% risk regimens not listed, added additional risk factors to primary prophylaxis, added hospitalized to treatment of neutropenia, added stem cell transplant indication, removed progenitor cell transplant indication, removed non-myeloid malignancy indication, added severe chronic neutropenia for Neupogen/Zarxio
Revised: 10/8/18 – Added Granix to cancer diag.; added Neulasta to secondary prophylaxis, treatment of FN, dose dense therapy, stem cell transplant, Leukemia/MDS, lymphoma and radiation diags.; added Leukine delayed neutrophil recovery or graft failure indication
Revised: 11/26/18 – added Fulphila to policy
Revised: 2/6/19 – removed A(N)CVB due to no availability in USA
Reviewed: 3/1/19 – annual review
Revised: 3/21/19 – added Nivestym to policy
Revised: 5/24/19 – added Udenyca to policy, corrected 2 typos
Revised: 10/8/19 – corrected "supported" typo throughout policy
Revised: 3/1/20 – annual review, added GHP Kids

Revised: 7/28/20 – added Ziextenzo to policy, updated QL to 1 per 14 days, added failure of biosimilar
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 7/20/22 – added Releuko and Nyvepria to policy, renamed policy
Reviewed: 3/1/23 – annual review
Revised: 10/6/23 – updated signature title; added Fylnetra, Stimufend, and Rolvedon to policy
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 163.0**

**SECTION: Commercial Drug**
**SUBJECT: Neupro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Neupro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Neupro may be made for members who meet the following criteria:

- Medical record documentation therapeutic failure on, intolerance to, or contraindication to pramipexole **AND** ropinirole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Neupro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

pramipexole, ropinirole, ropinirole ER

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

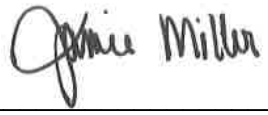
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 163.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Neupro**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/8/08 |
| Revised: | 11/21/12 – updated Mirapex and Requip to generic alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 164.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Veregen**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Veregen for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Veregen may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is immunocompetent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to podofilox solution/Condylox gel **AND** imiquimod (generic Aldara)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Veregen will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

podofilox solution, Condylox gel, imiquimod (generic Aldara)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

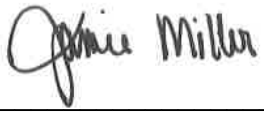
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 164.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Veregen**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 3/1/11 – annual review-updated with generic Aldara |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 10/7/13 – removed Neupro from policy |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated criteria format |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 165.0**

**SECTION: Commercial Drug**
**SUBJECT: Sodium Oxybate (generic Xyrem)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sodium oxybate (generic Xyrem) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of sodium oxybate (generic Xyrem) may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on modafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 18 mL per day, 30 day supply per fill

**AUTHORIZATION DURATION:**

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

If an exception is made, sodium oxybate (generic Xyrem) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

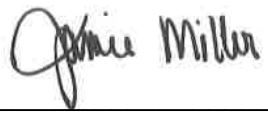
**FORMULARY ALTERNATIVES:**

armodafinil*, modafinil*, dextroamphetamine, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 7/10 – added phone number of the Xyrem pharmacy |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions, updated alternatives |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, removed non-FDA approved FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, update criteria format |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – removed REMS criteria, updated FA criteria, updated FA, added QL |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 165.0**

**SECTION: Commercial Drug**
**SUBJECT: Sodium Oxybate (generic Xyrem)**

Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – added authorization duration, updated FA
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title; updated to generic

Geisinger

**POLICY NUMBER: 167.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sildenafil (generic Revatio) and Liqrev**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sildenafil (generic Revatio) and Liqrev for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of sildenafil (generic Revatio) or Liqrev may be made for members who meet the following criteria:

- Medical record documentation that sildenafil is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
- See no medical record documentation of organic nitrate therapy **AND**
- If request is for sildenafil 10 mg/mL (generic Revatio): Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Liqrev

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for generic Revatio include generic only

If an exception is made, sildenafil (generic Revatio) or Liqrev will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

Geisinger

**POLICY NUMBER: 167.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sildenafil (generic Revatio) and Liqrev**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 6/10 – updated criteria to include pulm/cardio |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated policy title based on generic availability |
| Revised: | 9/22/14 – added Tracleer criteria, removed Tracleer as FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/21/16 – removed in combination with Tracleer |
| Reviewed: | 3/1/17 – annual review, clarified that policy is for generic Revatio |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 10/6/23 – updated signature title; added Liqrev to policy; added failure of Liqrev to generic Revatio |
| Revised: | 3/1/24 – annual review; updated authorization approval level |

Geisinger

**POLICY NUMBER: 168.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ambrisentan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ambrisentan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of ambrisentan may be made for members who meet the following criteria:

- Medical record documentation that ambrisentan is prescribed by a pulmonologist or cardiologist **AND**
- Medical record documentation of a diagnosis of functional class 2 or 3 pulmonary arterial hypertension **AND**
- Medical record documentation of one of the following:
  - Therapeutic failure on, intolerance to, or contraindication to sildenafil (generic Revatio) **OR**
  - Use as first line therapy in combination with tadalafil (generic Adcirca) in patients with WHO Group 1, function class II or III symptoms

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

If an exception is made, ambrisentan will be paid for under the member's prescription drug benefit

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 168.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ambrisentan |

**FORMULARY ALTERNATIVES:**

Uptravi*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*, Opsumit*, bosentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 6/10 – updated criteria to include pulm/cardio |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated Revatio to sildenafil based on generic availability |
| Revised: | 9/22/14 – removed failure of Tracleer, removed Tracleer from FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – updated formatting, added use as first line therapy in combo with Adcirca |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/22/16 – added QL, updated FA |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, defined PA abbrev. |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Letairis to generic ambrisentan, updated all others w/ available generics |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 169.0**

**SECTION: Commercial Drug**
**SUBJECT: Ventavis**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ventavis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ventavis may be made for members who meet the following criteria:

- Medical record documentation that Ventavis is prescribed by a pulmonologist or cardiologist **AND**
- Medical record documentation of a diagnosis of functional class 3 or 4 pulmonary arterial hypertension **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sildenafil* **AND** bosentan*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Ventavis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

sildenafil*, Liqrev*, bosentan* oral tablet, Tracleer Soluble oral tablet*

*prior authorization required

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 169.0**

**SECTION: Commercial Drug**
**SUBJECT: Ventavis**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 6/10 – updated criteria to include pulm/cardio |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review |
| Revised: | 3/1/13 – annual review, updated logo |
| Revised: | 3/1/14 – annual review, updated Revatio to sildenafil based on generic availability |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, added PA indicator to Tracleer |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Tracleer tablet to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 170.0**

**SECTION: Commercial Drug**
**SUBJECT: Treprostinil**
**(generic Remodulin)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for treprostinil (generic Remodulin) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of treprostinil (generic Remodulin) may be made for members who meet the following criteria:

- Medical record documentation that treprostinil is prescriber by a pulmonologist or cardiologist **AND**
- Medical record documentation that treprostinil is being administered subcutaneously **AND**
- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to, or use in combination with sildenafil (generic Revatio) **AND** an appropriate second line agent (an endothelin receptor antagonist or Uptravi) used with sildenafil (generic Revatio)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

If an exception is made, treprostinil (generic Remodulin) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 170.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Treprostinil<br>(generic Remodulin) |

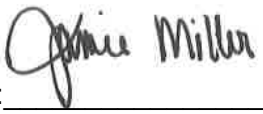
**FORMULARY ALTERNATIVES:**

Uptravi*, Orenitram*, Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, bosentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 6/10 – updated criteria to include pulm/cardio |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and policy definitions |
| Revised: | 3/1/14 – annual review, updated formatting, updated Revatio to sildenafil |
| Revised: | 9/22/14 – removed failure of Tracleer, removed Tracleer from FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/15 – annual review, added prior authorization note |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – revised FA requirement, updated FA |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Remodulin to generic treprostinil, updated all others w/ available generics |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 172.0**

**SECTION: Commercial Drug**
**SUBJECT: Sapropterin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sapropterin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of sapropterin may be made for members who meet the following criteria:

- Medical record documentation that sapropterin is prescribed by a metabolic specialist **AND**
- Medical record documentation of a diagnosis of hyperphenylalaninemia (baseline blood Phe level greater than or equal to 360 µmol/L) **AND**
- Medical record documentation of baseline Phe level **AND**
- Medical record documentation that the member is on and compliant with a Phe-restricted diet

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

**AUTHORIZATION DURATION:** Approval for new starts will be given for an initial authorization duration of eight (8) weeks. For continuation of coverage, the following criteria is required:

- Medical record documentation of a response to sapropterin defined by a reduction in blood Phe levels from baseline **OR**
- Medical record documentation of an increase in Phe tolerance (addition of Phe in diet with stable Phe level)

After the initial 8 week approval, subsequent approvals will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring the following:

- Medical record documentation of a sustained reduction in blood Phe levels **OR**
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in Phe tolerance

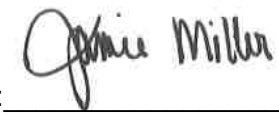
If an exception is made, sapropterin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, updated subject to Kuvan |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 5/29/19 – updated auth duration, updated baseline Phe level to 360 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Kuvan to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 172.0**

**SECTION: Commercial Drug**
**SUBJECT: Sapropterin**

Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 173.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Somatuline Depot**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Somatuline Depot for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Somatuline Depot may be made for members who meet the following criteria:

- Medical record documentation of treatment of an acromegalic patient who has had an inadequate response to or cannot be treated with surgery and/or radiotherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Somatuline Depot will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

octreotide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 173.0**

**SECTION: Commercial Drug**
**SUBJECT: Somatuline Depot**

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, update policy formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 174.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tasigna**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tasigna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tasigna may be made for members who meet the following criteria:

- Medical record documentation that Tasigna is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the use of Tasigna to treat newly diagnosed (not previously treated) chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in adult or pediatric patients greater than or equal to 1 year of age **OR**
- Medical record documentation of the use of Tasigna to treat chronic or accelerated phase Ph+ CML in adult patients with resistance to prior therapy including Gleevec (imatinib) **OR**
- Medical record documentation of the use of Tasigna to treat chronic or accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in pediatric patients greater than or equal to 1 year of age with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg capsule: 4 capsules per day, 30 day supply per fill
  - 150 mg and 200 mg capsule: 4 capsules per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Tasigna is configured as a prior authorization for new starts only. Tasigna will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Tasigna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

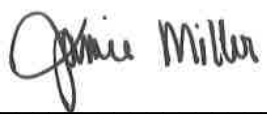
**FORMULARY ALTERNATIVES:**

Gleevec (imatinib), Sprycel*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 174.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tasigna**

| | |
|---|---|
| Devised: | 7/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 10/10 – updated to add new FDA indication per rec. from P&T |
| Reviewed: | 3/1/11—annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, updated policy formatting |
| Revised: | 3/24/16 – removed copay/15 day supply requirement, removed QL indicator from FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, changed Gleevec to imatinib |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language |
| Revised: | 5/31/18 – added adult/pediatric to newly diagnosed CML, added adult to failure of Gleevec, defined imatinib, pediatric CML with prior TKI therapy, updated FA, added QL |
| Revised: | 3/1/19 – annual review, defined abbreviations, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added treatment of accelerated phase Ph+ CML, added PANSO note, removed auth duration and added re-auth criteria |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 175.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lapatinib**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lapatinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of lapatinib may be made for members who meet the following criteria:

- Medical record documentation that lapatinib is prescribed by an oncologist **AND**
- Medical record documentation of use in combination with letrozole for the treatment of postmenopausal women with hormone receptor-positive (HER2+) metastatic breast cancer **OR**
- Medical record documentation of use in combination with capecitabine for advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor type 2 (HER2) and have received prior therapy including an anthracycline, a taxane, and trastuzumab (Herceptin)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Lapatinib is configured as a prior authorization for new starts only. Lapatinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved lapatinib will be paid for under the member's prescription drug benefit.

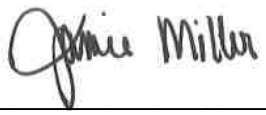
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/08
Reviewed: 4/09 – annual review
Revised 2/10 – added Femara combination agent
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated alternatives
Revised: 3/29/12 – added failure of an anthracycline to criteria #4
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 5/4/13 – updated criteria to reflect age requirements, fixed typo

Geisinger

**POLICY NUMBER: 175.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lapatinib**

| | |
|---|---|
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – added authorization duration |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather info |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, defined abbreviations, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Tykerb to generic |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 177.0**

**SECTION: Commercial Drug**
**SUBJECT: Xifaxan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xifaxan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xifaxan may be made for members who meet the following criteria:

**Traveler's Diarrhea**

- Medical record documentation of use for treatment of travelers' diarrhea **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin and one oral fluoroquinolone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- Add ST, PA, PE, OQL, and 3 tablets per day, min/max day supply 3
- QL FOR LETTER: 3 tablets per day, 3 day supply per fill

**AUTHORIZATION DURATION:** 3 days, RX count 1

**Hepatic Encephalopathy**

- Medical record documentation of use for the treatment of hepatic encephalopathy **AND**
- Medical record documentation of concomitant therapy with lactulose or medical record documentation of therapeutic failure on, intolerance to, or contraindication to lactulose

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**Irritable Bowel Syndrome with Diarrhea (IBS-D)**

- Medical record documentation of a diagnosis of moderate to severe irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation that the member is at least 18 years of age **AND**
- Medical record documentation that the correct Food and Drug Administration (FDA) approved strength/dosing is being prescribed (550 mg three times daily for 14 days) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dicyclomine **AND** loperamide

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- Add Treat As "Include" Process Modifier, Ignore Misc Handler, and 3 tablets per day, min/max day supply 14
- QL FOR LETTER: 3 tablets per day, 14 day supply per fill

**AUTHORIZATION DURATION:** 14 days, RX count 1

Reauthorization will require the following:

- Medical record documentation that the patient is having a recurrence of symptoms related to irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation that the patient has not received more than two previous courses of Xifaxan treatment for irritable bowel syndrome with diarrhea (IBS-D)

**NOTE:** Patients who experience recurrence of symptoms can be retreated up to two times, for a maximum of three cycles.

**Small Intestinal Bacterial Overgrowth**

- Medical record documentation of a diagnosis of small intestinal bacterial overgrowth **AND**
- Medical record documentation that the bacteria is hydrogen predominant as evidenced by a hydrogen breath test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- Add Treat As "Include" Process Modifier, Ignore Misc Handler, and 3 tablets per day, min/max day supply 14
- QL FOR LETTER: 3 tablets per day, 14 day supply per fill

**AUTHORIZATION DURATION:** 14 days, RX count 1

If an exception is made, Xifaxan will be paid for under the member's prescription drug benefit.

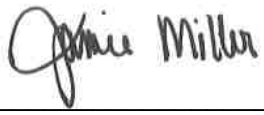
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Travelers Diarrhea: ciprofloxacin, azithromycin, levofloxacin
Hepatic encephalopathy: lactulose
irritable bowel syndrome with diarrhea (IBS-D): dicyclomine, loperamide
Small Intestinal Bacterial Overgrowth (SIBO): ciprofloxacin, metronidazole, neomycin, amoxicillin-clavulanate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Revised: | 4/10 – updated criteria to include HE and updated alternatives |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 9/18/15 – added IBS-D indication criteria, updated formulary alternatives |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 177.0**

**SECTION: Commercial Drug**
**SUBJECT: Xifaxan**

| | |
|---|---|
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated criteria format of travelers' diarrhea |
| Revised: | 3/1/19 – annual review, defined abbreviations, added IBS-D note |
| Revised: | 5/24/19 – updated policy format, added QL/duration & clarified 1 FQ for travelers' diarrhea |
| Revised: | 7/24/19 – corrected typo, added SIBO indication |
| Revised: | 01/21/20- updated authorization duration |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL/auth duration Statements |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated auth entry parameters |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 178.0**

**SECTION: Commercial Drug**
**SUBJECT: Aformoterol & Formoterol Nebulization Solution**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for aformoterol and formoterol nebulization solution for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of aformoterol or formoterol nebulization solution may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Serevent **OR** that member is unable to use an inhaler

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, aformoterol or formoterol nebulization solution will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Serevent

Geisinger

**POLICY NUMBER: 178.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aformoterol & Formoterol Nebulization Solution**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 1/25/17 – removed failure of Foradil due to products discontinuation |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, update format of criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Brovana & Perforomist to generic; added generic only |
| Revised: | 3/1/24 – annual review; updated signature title; corrected typo |

Geisinger

**POLICY NUMBER: 179.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lidocaine Patch**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lidocaine patch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of lidocaine patch may be made for members who meet the following criteria:

- Medical record documentation of a Food and Drug Administration (FDA) approved indication (postherpetic neuralgia) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a gabapentinoid (gabapentin or pregabalin)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

If an exception is made, lidocaine patch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

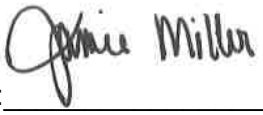
**FORMULARY ALTERNATIVES:**

gabapentin, pregabalin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 179.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lidocaine Patch** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/08 |
| Reviewed: | 4/09 – annual review |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated policy title based on generic availability |
| Revised: | 3/1/15 – annual review, updated signature, added postherpetic neuralgia |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, defined FDA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/6/22 – added failure of gabapentinoids, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 180.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sumatriptan/Naproxen**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sumatriptan/naproxen for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 296.0 Triptan Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
   C. In accordance with current standards of medical practice;
   D. Not primarily for the convenience of the Member, or the Member's Provider; and
   E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of sumatriptan/naproxen may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of migraine **AND**
- Member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to (two) formulary triptans (one of which must be sumatriptan) with concurrent use of naproxen **OR** if member is 12 to less than 18 years of age, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rizatriptan AND almotriptan with concurrent use of naproxen

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 16 doses per 28 days (Dose limit applies across all oral triptan products.)

If an exception is made, sumatriptan/naproxen will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 180.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Sumatriptan/Naproxen |

**FORMULARY ALTERNATIVES:**

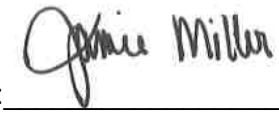
**Members greater than or equal to 18 years of age**: naproxen, sumatriptan**, Cafergot, rizatriptan**, Migranal, DHE 45, naratriptan**, almotriptan**

**Members 12 to less than 18 years of age**: naproxen, rizatriptan**, almotriptan**

** quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/09 |
| Reviewed: | 4/09 – annual review |
| Revised: | 5/09 – updated QL |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review-updated generics |
| Revised: | 9/11 – updated criteria. Removed Midrin and ergot derivatives from criteria |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo, definitions, and alternatives |
| Revised: | 9/25/13 – added quantity limit |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 9/19/15 – added pediatric indication, updated formulary alternatives |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Treximet to generic, updated FA, removed QL indicator from criteria |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 180.0**

**SECTION: Commercial Drug**
**SUBJECT: Sumatriptan/Naproxen**

Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 182.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Amlodipine/Olmesartan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for amlodipine/olmesartan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of amlodipine/olmesartan may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary angiotensin receptor blockers, one of which must be olmesartan, used in combination with amlodipine

If an exception is made, amlodipine/olmesartan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

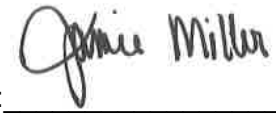
**FORMULARY ALTERNATIVES:**

olmesartan and amlodipine, losartan and amlodipine, irbesartan and amlodipine, valsartan and amlodipine, candesartan and amlodipine, telmisartan and amlodipine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 182.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Amlodipine/Olmesartan** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/09 |
| Reviewed: | 3/10 – annual review |
| Revised | 4/10 – updated alternatives |
| Revised: | 3/1/11 – annual review, updated alts |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review |
| Revised: | 12/1/14 – added failure of irbesartan, updated formulary alternatives, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, added valsartan and amlodipine to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – updated policy from Azor to amlodipine/olmesartan |
| Revised: | 3/27/17 – failure of valsartan |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 5/29/19 – deleted note, updated to failure of 3 preferred ARBs |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 183.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sancuso**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sancuso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Sancuso may be made for members who meet **ALL** of the following criteria:

- Medical record documentation of administration of a moderately to highly emetogenic chemotherapy for up to 5 consecutive days **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ondansetron and oral granisetron

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 patches per 28 days

If an exception is made, Sancuso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ondansetron, granisetron**, aprepitant**

** quantity limits apply

Geisinger

**POLICY NUMBER: 183.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sancuso**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/09 |
| Reviewed: | 3/10 |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, updated Emend to a quantity limit |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added QL indicator to granisetron |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Emend to aprepitant |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 184.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Relistor Injection**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Relistor injection for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Relistor Injection may be made for members who meet **ALL** of the following criteria:

**Chronic Non-Cancer Pain**

- Medical record documentation of a diagnosis of chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on two alternative laxative/bowel therapies **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Movantik

**Advanced Illness Receiving Palliative Care**

- Medical record documentation of advanced illness receiving palliative care **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on two alternative laxative/bowel therapies

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 12 mg dose: 0.6 mL (1 syringe) per day
  - 8 mg dose: 6 mL (15 syringes) per 30 days

If an exception is made, Relistor will be paid for under the member's prescription drug benefit.

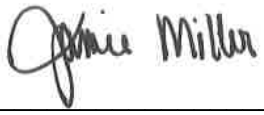
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Advanced Illness Receiving Palliative Care: lactulose
Chronic Non-Cancer Pain: lubiprostone, lactulose, Movantik

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/09 |
| Revised: | 5/09 – fixed typo |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 1/25/13 – removed polyethylene glycol from alternatives and updated path |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 4/13/15 – added chronic non-cancer pain to policy |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 11/22/16 – removed copay per 14-day supply, updated QL, updated formatting, added failure of Amitiza/Movantik for chronic non-cancer pain, updated FA |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 4/6/18 – updated chronic pain diagnosis criteria to include prior cancer |
| Revised: | 3/1/19 – annual review, added QL approval note |

Geisinger

**POLICY NUMBER: 184.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Relistor Injection**

| | |
|---|---|
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Amitiza to lubiprostone |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 185.0**

**SECTION: Commercial Drug**
**SUBJECT: Promacta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Promacta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Promacta may be made for members who meet **ALL** of the following criteria:

**For Chronic Immune Thrombocytopenic Purpura (ITP)**

- Medical record documentation of a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) **AND**
- Medical record documentation that Promacta is prescribed by a hematologist **AND**
- Medical record documentation of a therapeutic failure on, or contraindication to ALL of the following: corticosteroids, immunoglobulins, and rituximab* **AND**
- Symptomatic ITP with bleeding symptoms and a platelet count of less than 30,000/µL **OR** a documentation history of significant bleeding and a platelet count of less than 30,000/µL **OR** a platelet count of less than 20,000/µL

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**AUTHORIZATION DURATION:** If an exception is made, Promacta will be authorized for an **initial period of three (3) months** and continued coverage will require medical record documentation of improvement in symptoms and platelet count response above 20,000/µL. Subsequent authorizations will be for a period of **six (6) months** and will then require medical record documentation of dosing to maintain a platelet count between 50,000/µL and 100,000/µL.

**For Chronic Hepatitis C**

- Medical record documentation of a diagnosis of chronic hepatitis C and plan to initiate or continue interferon-based therapy **AND**
- Medical record documentation of a platelet count of less than 50,000/µL **AND**
- Medical record documentation that Promacta is prescribed by a gastroenterologist, hematologist, hepatologist or infectious disease specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**AUTHORIZATION DURATION:** If approved, the authorization will be for a time period of 6 months.

**For Severe Aplastic Anemia**

- Medical record documentation that Promacta is prescribed is written by a hematologist **AND**
- Medical record documentation of a platelet count less than or equal to 30,000/µL **AND**
- Medical record documentation of a diagnosis of severe aplastic anemia **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of an inadequate response to at least one prior immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus, Atgam® [lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only]) **OR**
    - Medical record documentation that Promacta will be used as first line treatment in combination with standard immunosuppressive therapy (e.g. antithymocyte globulin [equine] and cyclosporine)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**AUTHORIZATION DURATION:** If an exception is made, Promacta will be authorized for an **initial period of six (6) months** and continued coverage will require medical record documentation of improvement in symptoms and a hematological response. Subsequent authorizations will be for a period of **six (6) months** and will then require medical record documentation of continued hematological response.

**NOTE:** Per UpToDate, hematologic response is defined as independence from transfusion, no need for additional immunosuppressive therapy, and/or improvement or peripheral blood counts to the point that they no longer meet criteria for severe aplastic anemia.

If an exception is made, Promacta will be paid for under the member's prescription drug benefit.

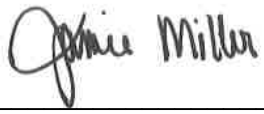
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 185.0 |
|---|---|
| POLICY AND PROCEDURE<br>PHARMACY<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Promacta |

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/09 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11—annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 5/4/13 – added chronic hepatitis C indication |
| Revised: | 10/7/13 – added prescribers and updated platelet units |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 12/1/14 – updated require failure on all FA, added platelet count to symptomatic bleeding for ITP, updated auth. dur. for ITP and HCV, updated signature |
| Revised: | 2/9/15 – corrected typo, added aplastic anemia indication |
| Revised: | 3/1/15 – annual review, updated formatting |
| Revised: | 11/20/15 – removed failure of splenectomy for chronic ITP |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters, corrected typo |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – added first line aplastic anemia indication, updated aplastic anemia auth duration to 6 months initial, added aplastic anemia note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 4/6/22 – updated Rituxan to rituximab, added platelet count less than 30,000/µL with history of bleeding, removed risk of bleeding from platelet count of less than 20,000/µL |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 187.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lacosamide**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lacosamide for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of lacosamide may be made for members who meet the following criteria:

**Partial-Onset Seizures**

- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 1 month **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**Primary Generalized Tonic-Clonic Seizures**

- Medical record documentation of a diagnosis of primary generalized tonic-clonic seizures **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (enter both 726000360003 & 726000360020), generic only

If an exception is made, lacosamide will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

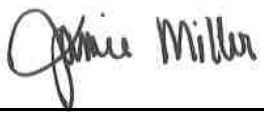
For patients aged ≥ 1 month of age: carbamazepine, levetiracetam IR, phenobarbital, phenytoin, pregabalin

Additional formulary alternatives for patients over certain ages: lamotrigine IR (2+), topiramate IR (2+), topiramate ER (2+)*, gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/09 |
| Reviewed: | 3/10 – annual review, updated alt. |
| Reviewed: | 3/1/11—annual review |
| Revised: | 2/12 – Added age requirement to criteria |
| Revised: | 3/12 – annual review, updated signature & alternatives |
| Revised: | 6/21/12 – clarified number of alternatives that must be failed |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |

Geisinger

**POLICY NUMBER: 187.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lacosamide**

| | |
|---|---|
| Revised: | 3/1/15 – annual review, updated signature, added language to first line of Section V |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 1/17/18 – decreased age to 4 years, updated FA by age, updated signature |
| Revised: | 3/1/18- annual review, updated formatting, added grandfather language |
| Revised: | 8/7/18 – updated FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/15/19 – corrected policy number typo, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 1/22/21 – added tonic-clonic indication, added MediSpan approval level |
| Revised: | 3/1/21 – annual review, updated logo |
| Revised: | 9/1/21 – corrected GPI for Vimpat Solution |
| Revised: | 1/5/22 – separated indications, updated partial-onset indication to 1 month, removed adjunct requirement from tonic-clonic, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated Vimpat to generic |
| Revised: | 3/1/24 – annual review; updated signature title; updated auth entry to generic only |

Geisinger

**POLICY NUMBER: 188.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Everolimus (generic Afinitor)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for everolimus (generic Afinitor) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of everolimus (generic Afinitor) may be made for members who meet the following criteria:

**Renal Cell Cancer**

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of renal cell cancer **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Sutent (sunitinib) or Nexavar (sorafenib) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Opdivo **OR** Cabometyx

**Breast Cancer**

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of hormone-receptor positive, HER-2 negative advanced breast cancer **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to previous endocrine therapy treatment **AND**
- Medical record documentation of everolimus (generic Afinitor) being used in combination with an aromatase inhibitor

**Neuroendocrine tumors of pancreatic origin**

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that is unresectable, locally advanced or metastatic (the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established) **OR**
- Medical record documentation of a diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal origin (GI) or lung origin that are unresectable, locally advanced, or metastatic

**Subependymal giant cell astrocytoma**

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection

**Renal angiomyolipoma and tuberous sclerosis complex/sporadic lymphangioleiomyomatosis**

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist, nephrologist, or urologist **AND**
- Medical record documentation of renal angiomyolipoma and tuberous sclerosis complex (TSC)/sporadic lymphangioleiomyomatosis, not requiring immediate surgery **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of at least one angiomyolipoma of greater than or equal to 3 cm in longest diameter on CT/MRI based on local radiology assessment

**NOTE:** Everolimus (generic Afinitor) will no longer be covered if there is medical record documentation of disease progression. Response is defined as: a greater than or equal to 50% reduction in angiomyolipoma volume, absence of new angiomyolipoma lesion greater than or equal to 1 cm, absence of kidney volume increase greater than or equal to 20%, or no angiomyolipoma related bleeding of greater than or equal to Grade 2.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Everolimus (generic Afinitor) is configured as a prior authorization for new starts only. Everolimus (generic Afinitor) will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, everolimus (generic Afinitor) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

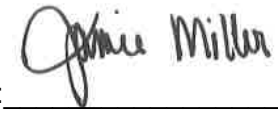
Renal cell cancer – sunitinib*, Nexavar*, Cabometyx*

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 188.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Everolimus (generic Afinitor)** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/09
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/01/12 – annual review, updated signature
Revised: 3/29/12 – added breast cancer, pancreatic neuroendocrine tumor, and subependymal giant cell astrocytoma indications
Revised: 7/18/12 – added renal angiomyolipoma and tuberous sclerosis complex/sporadic lymphangioleiomyomatosis indication
Revised: 9/17/12 – added hormone-receptor positive, HER-2 negative advanced breast cancer
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typos
Revised: 3/1/15 – annual review, updated signature, updated formatting
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed copay per 15 day supply requirement, removed quantity limit indicator from FA, added failure of Opdivo for RCC
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – added NET of GI or lung origin
Revised: 7/21/16 – added failure of Cabometyx to RCC
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 10/12/17 – updated FA, added AND to TSC criteria
Revised: 10/16/17 – corrected typo in NET criteria
Revised: 3/1/18 – annual review, updated signature, corrected typo, added grandfather language
Revised: 6/1/18 – updated prescriber bullet, added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/24/21 – updated policy to generic name, added one-time PA language to approval criteria, removed auth duration & added re-auth criteria
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 189.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aplenzin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aplenzin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Aplenzin may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of Major Depressive Disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to bupropion

**OR**

- Medical record documentation of a diagnosis of seasonal affective disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to bupropion XL

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Aplenzin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 189.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aplenzin**

**FORMULARY ALTERNATIVES:**

Major Depressive Disorder: bupropion, bupropion SR, bupropion XL
Seasonal Affective Disorder: bupropion XL

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/09 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 11/08/12 – added seasonal affective disorder indication and changed |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 190.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Mesalamine (generic Apriso)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for mesalamine (generic Apriso) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of mesalamine (generic Apriso) may be made for members who meet the following criteria:

- Medical record documentation of mild to moderate ulcerative colitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sulfasalazine **AND** mesalamine delayed release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, mesalamine (generic Apriso) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

mesalamine delayed release (generic Asacol or Lialda), balsalazide, Canasa Suppositories, Dipentum, mesalamine enema, mesalamine extended release (generic Pentasa 500 mg), Pentasa 250 mg, Rowasa, sulfasalazine, sulfasalazine enteric coated

Geisinger

**POLICY NUMBER: 190.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Mesalamine (generic Apriso)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/09 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated Asacol to HD as immed. release was D/C by manuf. |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, added Delzicol to formulary alternatives |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated Asacol to generic |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/18/20 – updated to generic |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY NUMBER: 192.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Fanapt**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fanapt for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fanapt may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of a contraindication, intolerance or therapeutic failure to all formulary agents (risperidone, olanzapine, quetiapine, aripiprazole and ziprasidone)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

If an exception is made, Fanapt will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

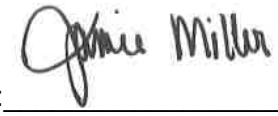
**FORMULARY ALTERNATIVES:**

risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole

| Geisinger | POLICY NUMBER: 192.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Fanapt |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/09 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11—annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, updated Geodon to ziprasidone & Seroquel to quetiapine |
| Revised: | 3/1/16 – annual review, changed Abilify to aripiprazole |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & formatting, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 195.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Silodosin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for silodosin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of silodosin may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alpha-blockers, one of which must be tamsulosin (Flomax)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, silodosin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

doxazosin, terazosin, tamsulosin, alfuzosin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 195.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Silodosin** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Revised: | 5/10 – combined Uroxatral and updated form. alt to include generic Flomax |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated from Rapaflo to new generic silodosin |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 196.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alogliptin and Saxagliptin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for alogliptin and saxagliptin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of alogliptin or saxagliptin may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Tradjenta

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, alogliptin or saxagliptin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Tradjenta, Jentadueto, Jentadueto XR

Geisinger

**POLICY NUMBER: 196.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alogliptin and Saxagliptin**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 2/12 – added Tradjenta |
| Revised: | 3/1/12 – annual review and updated signature |
| Revised: | 3/1/13 – annual review, updated logo, definitions, and alternatives |
| Revised: | 6/24/13 – added Nesina to policy |
| Revised: | 3/1/14 – annual review, updated formatting, updated Prandin to repaglinide |
| Revised: | 3/1/15 – annual review, updated signature, changed Actos to pioglitazone, added Jardiance, Tanzeum, & Victoza to FA, removed Byetta & Bydureon from FA |
| Revised: | 3/1/16 – annual review, added Toujeo, Synjardy, Invokana, and Invokamet to FA, updated PA/ST indicator |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined TZD, updated Nesina to alogliptin |
| Revised: | 11/28/17 – removed Tradjenta, removed diagnosis, updated signature, concomitant use with metformin/TZD, added failure of Januvia or Tradjenta, updated FA, added QL |
| Revised: | 2/9/18 – removed Januvia from criteria, updated FA |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note, removed step indicator from FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; removed reference to insomnia agents |
| Revised: | 11/1/23 – updated signature title; updated Onglyza to saxagliptin |
| Revised: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 197.0**

**SECTION: Commercial Drug**
**SUBJECT: Cimzia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cimzia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For Rheumatoid Arthritis**

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of rheumatoid arthritis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days

- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

**NOTE:** This product is billed per kit. Each kit contains two, 200mg syringes.

**RE-AUTHORIZATION CRITERIA:** Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*; Yusimry*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For Crohn's Disease**
An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cimzia is prescribed by a gastroenterologist **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

**NOTE:** This product is billed per kit. Each kit contains two, 200mg syringes.

**RE-AUTHORIZATION CRITERIA:** Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*; Yusimry*

*prior authorization required

**For Psoriatic Arthritis**
An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of psoriatic arthritis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

**NOTE:** This product is billed per kit. Each kit contains two, 200mg syringes.

**RE-AUTHORIZATION CRITERIA:** Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Enbrel*, Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*; Yusimry*, Otezla*, Skyrizi*, Tremfya*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For Ankylosing Spondylitis**
An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of ankylosing spondylitis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

**NOTE:** This product is billed per kit. Each kit contains two, 200mg syringes.

**RE-AUTHORIZATION CRITERIA:** Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*; Yusimry*, Enbrel*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For Plaque Psoriasis**
An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cimzia is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of psoriasis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *Two authorizations must be entered.*

1. In PA Hub: Add PA, number of claims authorized = 1, with a duration of one month
2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is one-day after loading dose ends.
    - QL FOR LETTER: 2 kits per 28 days

**NOTE:** This product is billed per kit. Each kit contains two, 200mg syringes.

**RE-AUTHORIZATION CRITERIA:** Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*; Yusimry*, Enbrel*, Otezla*, Skyrizi*, Tremfya*

*prior authorization required

**For Non-Radiographic Axial Spondylarthritis**
An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
- Medical record documentation of at least one of the following:
    - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
    - Sacroiliitis on magnetic resonance imaging (MRI)

**AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

**NOTE:** This product is billed per kit. Each kit contains two, 200mg syringes.

**RE-AUTHORIZATION CRITERIA:** Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

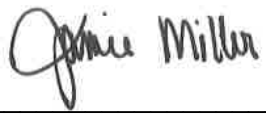
**FORMULARY ALTERNATIVES:**
none

If an exception is made, Cimzia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 9/17/12 – updated authorization duration and updated location |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/20/14 – updated policy format, added psoriatic arthritis & ankylosing spondylitis |
| Revised: | 9/22/14 – updated alternatives criteria for all indications, updated FA, added and updated criteria for RA and CD, expanded auth duration wording for RA and CD, updated auth duration wording for PsA and AS, and updated signature |
| Revised: | 11/21/14 – updated PsA FA criteria and removed leflunomide from FA list |
| Revised: | 2/9/15 – updated FA criteria for all indications, FA, and prescriber criteria for PsA |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 9/19/15 – removed joint count criteria from initial and renewal requirements |
| Revised: | 3/1/16 – annual review, updated policy formatting to improve readability |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated criteria format, added grandfather language |
| Revised: | 5/30/18 – added QL, added combination with other biologics, removed failure of Enbrel and added failure of Cosentyx (PsA, AS) |
| Revised: | 10/1/18 – removed failure of Enbrel and updated FA (RA) |
| Revised: | 12/28/18 – added PP indication, added QL note to all indications |
| Revised: | 3/1/19 – annual review, defined TNF |
| Revised: | 7/24/19 – added authorization parameters |

Revised: 10/1/19 – added non-radiographic axial spondylarthritis indication to policy
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered
Revised: 1/1/23 – updated to allow Cimzia after failure of 2 preferred agents & FA for RA, PsO, PsA, & AS
Revised: 3/1/23 – annual review; corrected typo in AS formulary alternatives
Revised: 3/1/24 – annual review; updated signature title; updated FA

Geisinger

**POLICY NUMBER: 198.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Simponi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Simponi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For Rheumatoid Arthritis:**

An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation that Simponi is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation of concomitant methotrexate use **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of rheumatoid arthritis **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (must enter 6627004000E5 & 6627004000D5), number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.5 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For Psoriatic Arthritis:**
An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation of age greater than or equal to 18 years
- Medical record documentation that Simponi is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of psoriatic arthritis **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (must enter 6627004000E5 & 6627004000D5), number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.5 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Otezla*, Skyrizi*, Tremfya*, Cosentyx*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For Ankylosing Spondylitis:**
An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Simponi is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of ankylosing spondylitis **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (must enter 6627004000E5 & 6627004000D5), number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.5 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Enbrel*, Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For Ulcerative Colitis:**
An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation that Simponi is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Humira* **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (must enter 6627004000E5 & 6627004000D5)

**QUANTITY LIMIT –**

1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 3, min day supply 28, max day supply 28, number of claims authorized = 1, with a duration of one month
    - QL FOR LETTER: Loading dose: 3 mL per 28 days; Maintenance dose: 1 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

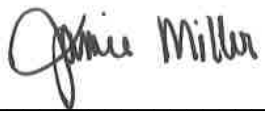
If an exception is made, Simponi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | **POLICY NUMBER: 198.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Simponi** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 9/17/12 – updated authorization duration and file location |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 7/29/13 – added ulcerative colitis indication |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 9/22/14 – specified & added criteria for each indication (except UC), updated wording for alternative criteria for UC updated auth duration wording for all indications, updated signature and FA |
| Revised: | 2/9/15 – updated FA criteria & FA for RA, PsA, and AS, and prescriber criteria for PsA. |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 09/19/15 – removed joint count criteria from initial and renewal requirements |
| Revised: | 03/01/16 – annual review, updated policy formatting to improve readability |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated criteria format, added grandfather language |
| Revised: | 5/31/18 – added combination with other biologic agents, removed failure of Enbrel and added failure of Cosentyx (PsA, AS), updated FA, added QL |
| Revised: | 10/1/18 – Removed failure of Enbrel & updated FA (RA) |
| Revised: | 3/1/19 – annual review, defined TNF |
| Revised: | 7/24/19 – updated QL and added authorization parameters |
| Revised: | 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry for PA NSO |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered |
| Revised: | 1/1/23 – updated to allow Simponi after failure of 2 preferred agents & FA for RA, PsA, & UC |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 199.0**

**SECTION: Commercial Drug**
**SUBJECT: Armodafinil**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for armodafinil for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of armodafinil may be made for members who meet the following criteria:

- Medical record documentation of:
  - a diagnosis of obstructive sleep apnea/hypopnea syndrome requiring treatment with nasal CPAP **OR**
  - a diagnosis of narcolepsy **OR**
  - a diagnosis of shift-work disorder

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, armodafinil will be paid for under the member's prescription drug benefit

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

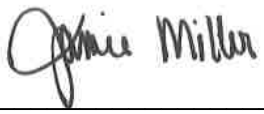
modafinil*

*prior authorization required

| Geisinger | POLICY NUMBER: 199.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Armodafinil |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 6/28/12 – removed Provigil from alternatives and added modafinil |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 11/15/13 – fixed typographical error, updated criteria to failure of modafinil |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, update policy formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Nuvigil to armodafinil |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/20/19 – removed failure of modafinil |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 201.0**

**SECTION: Commercial Drug**
**SUBJECT: Vigabatrin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for vigabatrin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of vigabatrin may be made for members who meet the following criteria:

**For Infantile Spasms**

- Medical record documentation that vigabatrin is prescribed by a neurologist **AND**
- Medical record documentation of use for infantile spasms

**For Refractory Complex Partial Seizures**

- Medical record documentation that vigabatrin is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of refractory complex partial seizures **AND**
- Medical record documentation that vigabatrin is being used concomitantly with another seizure control medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

If an exception is made, vigabatrin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

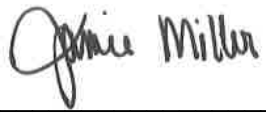
For patients > 2 years of age: carbamazepine IR, carbamazepine ER, lamotrigine IR, oxcarbazepine IR, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER (generic Qudexy XR)*

Additional formulary alternatives for patients over certain ages: gabapentin (3+), levetiracetam IR (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature & alternatives |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, corrected typo |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, removed carbatrol from FA, added tiagabine to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescriber, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Sabril to vigabatrin, updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 201.0**

**SECTION: Commercial Drug**
**SUBJECT: Vigabatrin**

Revised: 3/1/20 – annual review, added GHP Kids
Revised: 4/21/20 – added indication headers, removed failure of all alternatives, added partial seizure diagnosis, adjunctive therapy, and failure of 3 criteria, updated FA
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

| Geisinger | POLICY NUMBER: 202.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Asenapine |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for asenapine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of asenapine may be made for members who meet **BOTH** of the following criteria:

- Medical record documentation of schizophrenia or bipolar disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, asenapine will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

risperidone, olanzapine, aripiprazole, ziprasidone, quetiapine fumarate

| Geisinger | POLICY NUMBER: 202.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Asenapine |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature and alternatives |
| Revised: | 3/1/13 – annual review, updated logo, alternatives, and definitions |
| Revised: | 3/1/14 – annual review, updated alternatives based on generic Geodon and Seroquel |
| Revised: | 3/20/14 – updated criteria to require failure on 3 formulary alternatives |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, changed Abilify to aripiprazole |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Saphris to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 204.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Diclofenac Patch**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for diclofenac patch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of diclofenac patch may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (treatment of acute pain due to minor strains, sprains, and contusions) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) oral formulary NSAIDs

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 30 patches every 15 days

If an exception is made, diclofenac patch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

Geisinger

**POLICY NUMBER: 204.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Diclofenac Patch**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11—annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 2/1/14 – updated criteria to indicate number of formulary alternatives required |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature, added celecoxib to FA, updated formatting |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined FDA and approved indication |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Flector to generic diclofenac |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 205.0**

**SECTION: Commercial Drug**
**SUBJECT: Rufinamide**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for rufinamide for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of rufinamide may be made for members who meet the following criteria:

- Medical record documentation of use in adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children greater than or equal to 1 year of age and adults **OR**
- Medical record documentation of use in intractable epilepsy as defined as failure on two (2) formulary seizure medications

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, rufinamide will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

lamotrigine, topiramate, felbamate

| Geisinger | POLICY NUMBER: 205.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Rufinamide |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting |
| Revised: | 5/28/14 – added intractable epilepsy indication, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 6/8/15 – updated age requirement for LGS |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Banzel suspension to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated tablets to generic |
| Revised: | 3/1/23 – annual review; updated generic only approval to all dosage forms |
| Revised: | 3/1/24 – annual review; updated signature title |

| Geisinger | POLICY NUMBER: 206.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Febuxostat** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for febuxostat for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of febuxostat may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to allopurinol

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, febuxostat will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

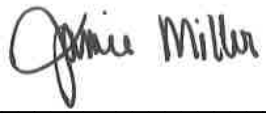
**FORMULARY ALTERNATIVES:**

allopurinol, probenecid

| Geisinger | **POLICY NUMBER: 206.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Febuxostat** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/10 |
| Reviewed: | 3/10 – annual review |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 2/12- removed probenecid failure from prior auth criteria |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature. |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Uloric to generic febuxostat |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 207.0**

**SECTION: Commercial Drug**
**SUBJECT: Pazopanib**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pazopanib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of pazopanib may be made for members who meet **ONE** of the following sets of criteria:

**Advanced Renal Cell Carcinoma with Clear Cell or Predominantly Clear Cell Histology**

- Medical record documentation that pazopanib is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma with clear cell or predominantly clear cell histology

**Advanced Renal Cell Carcinoma with Non-Clear Clear Histology**

- Medical record documentation that pazopanib is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma with non-clear cell histology **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, temsirolimus **AND** either sunitinib* **OR** sorafenib*

**Advanced Soft Tissue Sarcoma (STS)**

- Medical record documentation that pazopanib is prescribed by an oncologist **AND**
  - Medical record documentation of a diagnosis of advanced soft tissue sarcoma (STS) **AND**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior chemotherapy treatment

**NOTE:** Will not be approved for gastrointestinal stromal tumors (GIST) or adipocytic sarcoma.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Pazopanib is configured as a prior authorization for new starts only. Pazopanib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Votrient will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

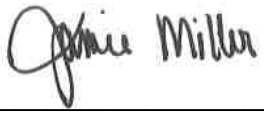
sunitinib*, sorafenib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 207.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Pazopanib** |

Signed: 

Title: Director, Pharmacy Services

Date: March 1, 2023

| | |
|---|---|
| Devised: | 3/10 |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 7/18/12 – added advanced soft tissue sarcoma indication |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, corrected typo |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – removed copay/15 day supply requirement, removed QL indicator from FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – added authorization duration |
| Revised: | 3/1/18 – annual review, updated signature, updated criteria format, added grandfather language |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA, added headers |
| Revised: | 3/1/23 – annual review; updated Sutent to sunitinib |
| Revised: | 3/1/24 – annual review; updated signature title; updated Votrient, Torisel, and Nexavar to generic |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 208.0**

**SECTION: Commercial Drug**
**SUBJECT: Arcalyst**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Arcalyst for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Arcalyst may be made for members who meet the following criteria:

**Cryopyrin-Associated Periodic Syndrome (CAPS)**

- Medical record documentation of diagnosis of Cryopyrin–Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation **AND**
- Medical record documentation that Arcalyst is prescribed by an immunologist, rheumatologist, or allergist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret **AND** Ilaris

**Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**

- Medical record documentation that Arcalyst is prescribed by or in consultation with a cardiologist or rheumatologist **AND**
- Medical record documentation of weight greater than or equal to 10 kg **AND**
- Medical record documentation of a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL1RN (Interleukin 1 Receptor Antagonist gene) **AND**
- Medical record documentation that remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) was induced by Kineret‡ **AND**
- Medical record documentation Arcalyst (rilonacept) is being used for maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret

[‡]**NOTE:** Inflammatory remission in clinical trial defined as having the following: normal acute-phase reactants (C-reactive protein (CRP) < 0.5 mg/dl), resolution of fever, skin rash and bone pain, and radiological evidence of no active bone lesions on x-ray.

**Recurrent Pericarditis (RP)**

- Medical record documentation that Arcalyst is prescribed by or in consultation with a cardiologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of Recurrent Pericarditis (RP) as evidenced by a recurrence of pericarditis after a symptom free interval of 4 to 6 weeks or longer following a documented episode of acute pericarditis[#] **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to colchicine **AND** a nonsteroidal anti-inflammatory drug (NSAID) or aspirin

[#]**NOTE:** The European Society of Cardiology (ESC) defines acute pericarditis to be an inflammatory pericardial syndrome diagnosed with at least 2 of the following 4 criteria: 1) pericarditic chest pain, 2) pericardial rubs, 3) new widespread ST elevations or PR depression on ECG or 4) pericardial effusion (new or worsening).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**QUANTITY LIMIT**

- **Initial Approval** – Two authorizations must be entered.
    1. In PA Hub: Add PA only for the approved authorization duration.
    2. In Darwin: Add Ignore Misc Handler, DS, 1 in max number of claims authorized, max quantity dispensed 4, min day supply 21, max day supply 21, with a duration of one-week.
        - QL FOR LETTER: Loading dose: 4 mL per 21 days; Maintenance dose: 4 mL per 28 days
- **Renewal –** No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.
    - QL FOR LETTER: 4 mL per 28 days

If an exception is made, Arcalyst will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

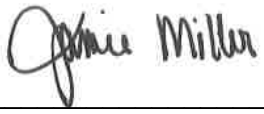
**FORMULARY ALTERNATIVES:**

CAPS: Kineret*, Ilaris*
DIRA: Kineret*
RP: colchicine, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin, aspirin

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/10
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 5/4/13 – updated alternatives language
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator
Reviewed: 3/1/17 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 208.0**

**SECTION: Commercial Drug**
**SUBJECT: Arcalyst**

| | |
|---|---|
| Revised: | 3/27/17 – removed COE requirement |
| Revised: | 6/2/17 – added failure of Kineret, removed bolded statement regarding Ilaris/Kineret |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 7/24/19 – added QL and authorization parameters |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 9/1/21 – added DIRA and RP indications, updated FA, updated auth duration |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered |
| Revised: | 3/1/23 – annual review; updated FA to define PA |
| Revised: | 3/1/24 – annual review; updated signature title; updated QL parameters |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 209.0**

**SECTION: Commercial Drug**
**SUBJECT: Tadalafil**
**(generic Adcirca)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tadalafil (generic Adcirca) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of tadalafil (generic Adcirca) may be made for members who meet the following criteria:

- Medical record documentation that tadalafil is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis pulmonary arterial hypertension (PAH) **AND**
- Medical record documentation that tadalafil will not be used concomitantly with organic nitrate therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

If an exception is made, tadalafil (generic Adcirca) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 209.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tadalafil<br>(generic Adcirca) |

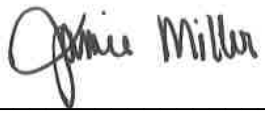
**FORMULARY ALTERNATIVES:**

Uptravi*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, bosentan*, sildenafil* (generic Revatio), Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/10 |
| Reviewed: | 3/1/11 – annual update |
| Revised: | 3/1/12- annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated Revatio to sildenafil, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – added 1st line therapy in combo w/ Letairis, removed 2 copay/34 day supply |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/22/16 – added QL, updated FA |
| Revised: | 3/1/17 – annual review, defined WHO |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed criteria, defined PA |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Adcirca to generic tadalafil, updated all others w/ available generics |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/20/23 – removed functional class requirement; removed failure of alts; added no nitrate combo |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 210.0**

**SECTION: Commercial Drug**
**SUBJECT: Tyvaso**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tyvaso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tyvaso may be made for members who meet the following criteria:

**Class III or IV Pulmonary Artery Hypertension**

- Medical record documentation that Tyvaso is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class III or IV pulmonary artery hypertension **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with sildenafil* **OR** bosentan*

**Pulmonary Hypertension associated with Interstitial Lung Disease**

- Medical record documentation that Tyvaso is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of pulmonary hypertension associated with interstitial lung disease (World Health Organization Group 3 Pulmonary Hypertension)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

If an exception is made, Tyvaso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 210.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tyvaso |

**FORMULARY ALTERNATIVES:**

Class III or IV Pulmonary Artery Hypertension: Uptravi*, Orenitram*, treprostinil (generic Remodulin)*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, tadalafil (generic Adcirca)*, sildenafil (generic Revatio)*, Liqrev*, bosentan*

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/10 |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated Revatio to sildenafil, updated formatting |
| Revised: | 9/22/14 – removed failure of Tracleer, removed Tracleer from FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 3/24/16 – removed 2 copay per 30 day supply requirement |
| Revised: | 5/1/16 – updated format, logo, & procedure, added authorization duration indicator |
| Revised: | 7/27/16 – added functional class IV, updated FA requirement, updated FA's |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria, defined PA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA to generic name |
| Revised: | 11/1/21 – added interstitial lung disease indication |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 213.0**

**SECTION: Commercial Drug**
**SUBJECT: Nebivolol**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for nebivolol for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of nebivolol may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary beta blocker agents

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, nebivolol will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

acebutolol, atenolol, atenolol-chlorthalidone, betaxolol, bisoprolol, bisoprolol-hctz, carvedilol, labetalol, metoprolol succinate, metoprolol tartrate, metoprolol-hctz, nadolol, pindolol, propranolol, propranolol sa, propranolol-hctz, sotalol, timolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 213.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Nebivolol** |

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/10 |
| Reviewed: | 3/1/11 – annual review |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added acebutolol, atenolol-Chlorthalidone, betaxolol, bisoprolol-hctz, carvedilol, labetalol, metoprolol tartrate, metoprolol-hctz, nadolol, pindolol, propranolol, propranolol-hctz, sotalol, timolol to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated 2 to two |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Bystolic to nebivolol |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated auth entry to generic only |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 218.0**

**SECTION: Commercial Drug**
**SUBJECT: Dabigaratan Capsules & Pradaxa Packets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for dabigatran capsules and Pradaxa Packets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of dabigatran capsules and Pradaxa Packets may be made for members who meet the following criteria:

- Medical record documentation of treatment to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation **OR**
- Medical record documentation of use for the treatment of deep vein thrombosis, pulmonary embolism, or for the reduction in the risk of recurrence of deep vein thrombosis and/or pulmonary embolism **OR**
- Medical record documentation of use for the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Eliquis **OR** Xarelto

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for dabigatran capsules add generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day

If an exception is made, dabigatran capsules and Pradaxa Packets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 218.0**

**SECTION: Commercial Drug**
**SUBJECT: Dabigaratan Capsules & Pradaxa Packets**

**FORMULARY ALTERNATIVES:**
Eliquis, Xarelto

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 12/10 |
| Reviewed: | 3/01/11 – annual review |
| Retired: | 6/8/11 |
| Revised: | 5/28/14 – updated criteria, updated signature, updated logo, updated policy format |
| Revised: | 3/1/15 – annual review, updated DVT/PE criteria to require failure on Eliquis |
| Revised: | 3/1/16 – annual review, removed Hep C/FDA definitions |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – added DVT/PE prophylaxis |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 1/17/18 – updated policy format, added step language, now requires failure of Eliquis OR Xarelto, added QL, updated signature |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; removed ST language due to NF status |
| Revised: | 3/1/24 – annual review; updated signature title; updated capsules to generic only |

Geisinger

**POLICY NUMBER: 223.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Acyclovir Cream and Penciclovir Cream**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for acyclovir cream and penciclovir cream for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of acyclovir cream or penciclovir cream, may be made for members who meet the following criteria:

**For the treatment of Cold Sores:**

- An exception for the coverage of **acyclovir cream** may be made for members who meet the following criteria:
  - Medical record documentation of a diagnosis of Cold Sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older **AND**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to:
    - Abreva (OTC), valacyclovir, **AND** famciclovir (famciclovir only if age greater than or equal to 18 years)

- An exception for the coverage of **penciclovir cream** may be made for members who meet the following criteria:
  - Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older **AND**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to:
    - Abreva (OTC), acyclovir cream (prior authorization required), valacyclovir, **AND** famciclovir (famciclovir only if age greater than or equal to 18 years)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 copay per package

If an exception is made, topical acyclovir or penciclovir cream will be paid for under the member's prescription drug benefit.

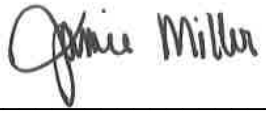
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Cold Sores: valacyclovir, famciclovir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/11 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 7/22/14 – removed approval with concomitant valacyclovir, updated FA and signature |
| Revised: | 3/1/15 – annual review, updated formatting |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 8/8/17 – added note to require famciclovir only if age greater than or equal to 18 years |

Revised: 3/1/18 – annual review, updated signature, corrected typo
Revised: 3/1/19 – annual review, renamed to generic acyclovir
Revised: 4/9/19 – updated Zovirax to acyclovir within Denavir criteria, defined *
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/29/20 – removed PA from acyclovir ointment, deleted genital herpes section of policy
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOB
Revised: 3/1/23 – annual review; updated Denavir to penciclovir & added generic only approval language
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 224.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Naproxen/esomeprazole**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for naproxen/esomeprazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of naproxen/esomeprazole may be made for members who meet the following criteria:

**Osteoarthritis, Rheumatoid Arthritis, and Ankylosing Spondylitis**

- Medical record documentation of a diagnosis of osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to naproxen and three (3) formulary PPI (proton pump inhibitor) agents used in combination

**Juvenile Idiopathic Arthritis**

- Medical record documentation of a diagnosis of juvenile idiopathic arthritis (JIA) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of weight greater than or equal to 38 kg **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to naproxen and three (3) formulary PPI (proton pump inhibitor) agents used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

If an exception is made, naproxen/esomeprazole will be paid for under the member's prescription drug benefit.

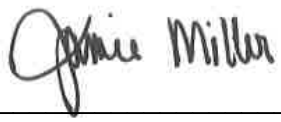
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

naproxen, omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/11 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, added rabeprazole to alternatives |
| Revised: | 3/1/16 – annual review, update bullet formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 11/27/17 – added indication headers, added JIA, added age & updated alt. bullet for OA, RA, and AS, added QL, updated signature |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Vimovo to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo |
| Reviewed: | 3/1/23 – annual review |

Geisinger

**POLICY NUMBER: 224.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Naproxen/esomeprazole**

Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 225.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alogliptin/Metformin and Saxagliptin/Metformin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for alogliptin/metformin and saxagliptin/metformin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of alogliptin/metformin or saxagliptin/metformin may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta in combination with metformin, Jentadueto, **OR** Jentadueto XR

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Saxagliptin/metformin 2.5-1000 mg: 2 tablets per day
  - Saxagliptin/metformin (all other strengths): 1 tablet per day
  - Alogliptin/metformin: 2 tablets per day

If an exception is made, alogliptin/metformin or saxagliptin/metformin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Tradjenta, metformin, Jentadueto, Jentadueto XR

Geisinger

**POLICY NUMBER: 225.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alogliptin/Metformin and Saxagliptin/Metformin**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/11 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 7/18/12 – added Jentadueto to policy, updated alternatives to include Janumet XR |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 6/24/13 – added Kazano to policy, updated formulary alternatives |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated PA requirements to ST |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Kazano to alogliptin/metformin |
| Revised: | 11/28/17 – added failure of Tradjenta products, updated FA/signature, added QL |
| Revised: | 2/9/18 – removed failure of sitagliptin, updated Tradjenta to combo with metformin, updated FA, corrected typo |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note, removed step indicator from FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 11/1/23 – updated signature title; updated Kombiglyze XR to saxagliptin/metformin |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 228.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Vilazodone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for vilazodone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of vilazodone may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, at least three antidepressant classes

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, vilazodone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 228.0 |
|---|---|
| POLICY AND PROCEDURE<br>PHARMACY<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Vilazodone |

**FORMULARY ALTERNATIVES:**

**SSRIs:** citalopram, fluoxetine, paroxetine, sertraline, escitalopram
**MAOIs:** phenelzine, tranylcypromine
**SNRIs:** venlafaxine hcl, venlafaxine er, duloxetine, desvenlafaxine (generic Pristiq)
**Tricyclics:** amitriptyline, nortriptyline, desipramine, doxepin, imipramine
**Bupropion:** bupropion hcl, bupropion xl, bupropion sr
**Other:** trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/11 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, added duloxetine to formulary alternatives |
| Revised: | 3/1/15 – annual review, updated signature, added escitalopram to alternatives |
| Revised: | 3/1/16 – annual review, updated bullet formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria & FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 6/4/21 – removed specific failure of bupropion, added QL |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 10/25/23 – updated signature title; update to generic only |
| Revised: | 3/1/24 – annual review; updated auth entry to GPI-12 |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 229.0**

**SECTION: Commercial Drug**
**SUBJECT: Caprelsa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Caprelsa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Caprelsa may be made for members who meet the following criteria:

- Medical record documentation that Caprelsa is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of medullary thyroid carcinoma in patients with unresectable, advanced, or metastatic disease

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 100 mg tablet: 2 tablets per day, 30 day supply per fill
  - 300 mg tablet: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Caprelsa is configured as a prior authorization for new starts only. Caprelsa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Caprelsa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

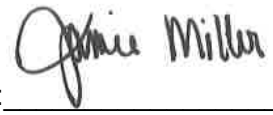
**FORMULARY ALTERNATIVES:**

Cometriq*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/11 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo, policy title and definitions |
| Revised: | 5/4/13 – added oncologist requirement, updated alternatives |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated bullet formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – added authorization duration |
| Revised: | 3/1/18 – annual review, updated signature & prescribed criteria, added grandfather language |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature title

Geisinger

**POLICY NUMBER: 236.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Spacers for MDI**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for spacers for MDI for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of a spacer for a metered dose inhaler (MDI) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on OptiChamber

**NOTE:** The member will be charged 1 copay per unit

**MEDISPAN AUTHORIZATION LEVEL:** NDC-9

**QUANTITY LIMIT:** Members are limited to 2 spacers/masks per calendar year

If an exception is made, a Spacer for an MDI will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

OptiChamber

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

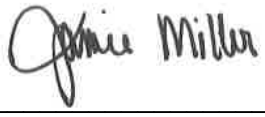
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 236.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Spacers for MDI**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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|---|---|
| Devised: | 9/11 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, added note and auth duration indicator |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo, defined MDI |
| Revised: | 3/1/19 – annual review, defined MDI |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY NUMBER: 237.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Roflumilast**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for roflumilast for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of roflumilast may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one long acting antimuscarinic antagonist and one long acting beta agonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, roflumilast will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Long Acting Beta Agonists:** Serevent Diskus
**Beta Agonist/Corticosteroid Combinations:** fluticasone/salmeterol, Wixela Inhub, Breo Ellipta
**Short Acting Anticholinergics:** ipratropium/albuterol nebulizer, Combivent, Atrovent
**Long Acting Antimuscarinic Antagonists:** Spiriva, Incruse Ellipta
**Anticholinergic/Beta Agonist Combinations:** Anoro Ellipta
**Anticholinergic/Beta Agonist/Long Acting Anticholinergic Combinations:** Trelegy Ellipta

Geisinger

**POLICY NUMBER: 237.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Roflumilast**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/12 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, removed Symbicort from FA, added Breo Ellipta & Tudorza to FA |
| Revised: | 3/1/15 – annual review, updated signature, remove Tudorza Pressair from alternatives |
| Revised: | 3/1/16 – annual review, updated FA bullet formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 12/7/16 – removed Foradil from FA |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, defined COPD, updated FA |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 11/21/19 – updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 10/12/20 – updated from failure of Spiriva to one LAMA, updated FA |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Daliresp to roflumilast & added generic only approval language |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 238.0**

**SECTION: Commercial Drug**
**SUBJECT: Dutasteride/Tamsulosin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for dutasteride/tamsulosin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of dutasteride/tamsulosin may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of benign prostatic hypertrophy **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a 3-month trial with formulary 5-alpha reductase inhibitors in combination with formulary alpha 1A antagonists

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, dutasteride/tamsulosin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**5-alpha reductase inhibitors:** finasteride, dutasteride
**Alpha 1A antagonists:** alfuzosin, doxazosin, tamsulosin, terazosin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 238.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Dutasteride/Tamsulosin** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/12 |
| Revised: | 3/1/12 – annual review, updated signature |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated Avodart to dutasteride |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Jalyn to dutasteride/Tamsulosin |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 239.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Dificid**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dificid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Dificid may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Clostridium difficile associated diarrhea in members greater than or equal to 6 months of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to vancomycin capsules. Must try at least two courses of treatment, one course must be a taper or pulsed regimen

**OR**

- Initiation of therapy with Dificid in the hospital

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tablets: 20 tablets per fill
  - Suspension: 150 mL per fill

**AUTHORIZATION DURATION:** 10 days, RX count 1

If a formulary exception is approved, Dificid will be paid for under the member's prescription drug benefit.

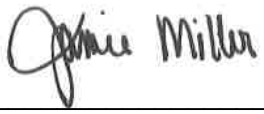
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 239.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Dificid |

**FORMULARY ALTERNATIVES:**
vancomycin capsules, metronidazole, Firvanq

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/29/12 |
| Revised: | 3/1/13 – annual review, updated logo |
| Revised: | 3/1/14 – annual review, added prescriber statement |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 3/1/16 – annual review, updated bullets to include “medical record documentation,” changed Vancocin to vancomycin |
| Revised: | 5/1/16 – updated format, logo, & procedure, added authorization duration indicator |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 8/21/18 – removed failure of metronidazole |
| Revised: | 3/1/19 – annual review, added QL approval note, added RX count |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/28/20 – updated age to 6 months |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs and added suspension QL |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 242.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Bupropion XL**
**(generic Forfivo XL)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for bupropion XL (generic Forfivo XL) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of bupropion XL (generic Forfivo XL) may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of Major Depressive Disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to bupropion xl

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved bupropion XL (generic Forfivo XL) will be paid for under the member's prescription drug benefit.

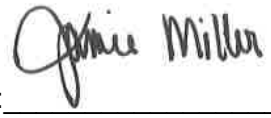
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 242.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Bupropion XL<br>(generic Forfivo XL) |

**FORMULARY ALTERNATIVES:**
bupropion, bupropion sr, bupropion xl

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/29/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, updated title |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated QL to daily dose, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Forfivo to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; corrected typo |

Geisinger

**POLICY NUMBER: 243.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Pitavastatin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pitavastatin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 469.0 Statin Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of pitavastatin may be made for members who meet the following criteria:

- Medical record documentation of member age greater than or equal to 8 years **AND**
- *For members greater than or equal to 10 years of age:* Medical record documentation of intolerance to, contraindication to, or therapeutic failure (including up-to-date laboratory values) to reach goal low-density lipoprotein (LDL) (per NCEP guidelines) after titration to tolerated doses of simvastatin **AND** atorvastatin **AND** rosuvastatin **OR**
- *For members greater than or equal to 8 years of age to less than 10 years of age:* Medical record documentation of intolerance to, contraindication to, or therapeutic failure (including up-to-date laboratory values) to reach goal low-density lipoprotein (LDL) (per NCEP guidelines) after titration to tolerated doses of rosuvastatin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved pitavastatin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Greater than or equal to 8 years of age to 10 years of age: rosuvastatin, pravastatin
Greater than or equal to 10 years of age: atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin

| Geisinger | POLICY NUMBER: 243.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Pitavastatin |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/29/12 |
| Revised: | 1/25/13 – indicated prior authorization required for Crestor |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – updated Crestor to rosuvastatin |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, defined LDL |
| Revised: | 10/1/19 – added age criteria, split FA criteria by age, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated to generic |

Geisinger

**POLICY NUMBER: 244.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Deferiprone Tablets, Ferriprox Twice-A-Day Tablets, and Ferriprox Oral Solution**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for deferiprone tablets, Ferriprox Twice-A-Day tablets, and Ferriprox oral solution for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of deferiprone tablets, Ferriprox Twice-A-Day tablets, or Ferriprox oral solution may be made for members who meet the following criteria:

- Medical record documentation that deferiprone is prescribed by a hematologist **AND**
- Medical record documentation of being used for the treatment of transfusional iron overload due to one of the following:
  - Thalassemia syndromes **OR**
  - Sickle cell disease and other anemias*

**AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to deferasirox (generic Exjade) **AND**
- Medical record documentation of absolute neutrophil count (ANC) greater than 1.5 x $10^9$/L

***NOTE:** Safety and effectiveness of deferiprone have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for deferiprone three-times-a-day add generic only

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level > 300 mcg/L.

If a formulary exception is approved, deferiprone tablets, Ferriprox Twice-A-Day tablets, or Ferriprox oral solution will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

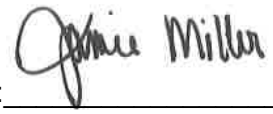
**FORMULARY ALTERNATIVES:**

deferasirox (generic Exjade)*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/29/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo |
| Revised: | 3/1/14 – annual review, indicated PA required on Exjade |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added "medical record documentation of" to Exjade bullet |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 8/8/17 – added authorization duration |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed criteria, defined Unicode |
| Revised: | 3/1/19 – annual review, removed distribution information |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Exjade to generic |
| Revised: | 11/19/21 – added indication for sickle cell disease & other anemias, added note |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated three-times-a-day tablets to generic only |

Geisinger

**POLICY NUMBER: 245.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Erivedge**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Erivedge for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Erivedge may be made for members who meet the following criteria:

- Medical record documentation that Erivedge is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of metastatic basal cell carcinoma, or locally advanced basal cell carcinoma that has recurred following surgery or for patients who are not candidates for surgery, and who are not candidates for radiation **AND**
- Medical record documentation of Erivedge treatment supported by multidisciplinary board consultation or a second dermatologist/oncologist per National Comprehensive Cancer Network (NCCN) guidelines

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Erivedge is configured as a prior authorization for new starts only. Erivedge will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Erivedge will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Odomzo*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/29/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 11/20/15 – updated diagnosis requirements, added age requirement, updated FA |
| Reviewed: | 3/1/16 – annual review |

Revised: 5/1/16 – updated format, logo, & procedure, updated note to authorization duration
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber & age criteria, removed QL indicator, updated QL to daily dosing
Revised: 3/1/19 – annual review, added QL approval note, removed distribution information
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – updated QL to reflect package size of 28 capsules
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; defined NCCN
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 246.0**

**SECTION: Commercial Drug**
**SUBJECT: Inlyta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inlyta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Inlyta may be made for members who meet the following criteria:

- Medical record documentation that Inlyta is prescribed by an oncologist **AND**
- Medical record documentation of advanced renal cell carcinoma (RCC) **AND**
- Medication record documentation of one of the following:
    - Medical record documentation of failure of one prior systemic therapy

    **OR**
    - Use as first-line treatment **AND**
    - Use in combination with pembrolizumab (Keytruda)

    **OR**
    - Use as first-line treatment **AND**
    - Used in combination with avelumab (Bavencio)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 1 mg tablet: 6 tablets per day, 30 day supply per fill
    - 5 mg tablet: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Inlyta is configured as a prior authorization for new starts only. Inlyta will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Inlyta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

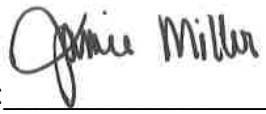
**FORMULARY ALTERNATIVES:**

everolimus (generic Afinitor)*, Avastin*, sorafenib*, Proleukin, sunitinib*, temsirolimus*, pazopanib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/29/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated CuraScript to Accredo

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 246.0**

**SECTION: Commercial Drug**
**SUBJECT: Inlyta**

| | |
|---|---|
| Revised: | 5/1/16 – updated format, logo, & procedure, added authorization duration indicator |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note, removed distribution information |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – added first line treatment with Keytruda or Bavencio |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY NUMBER: 247.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: H.P. Acthar Gel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for H.P. Acthar Gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of H.P. Acthar Gel may be made for members who meet the following criteria:

**For infantile myoclonic seizures (infantile spasms):**

- Documentation that the member is less than 2 years of age **AND**
- Medical record documentation that H.P. Acthar Gel is prescribed by a neurologist **AND**
- Documentation of diagnosis confirmed by electroencephalogram (EEG)

**For all other Indications:**

- GHP considers H.P. Acthar Gel **not medically necessary** for diagnostic testing of adrenocortical function because it has not been shown to be superior to Cosyntropin for this test.
- GHP considers H.P. Acthar Gel **not medically necessary** for corticosteroid-responsive conditions because it has not been proven to be more effective than corticosteroids for these indications.
- GHP considers H.P. Acthar Gel **experimental and investigational** or unproven for all other indications because its effectiveness for these indications has not been established in peer-reviewed literature citing well-designed clinical trials to indicated that the member's healthcare outcome will be improved by using H.P. Acthar Gel.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Treatment period is defined as 28 days; a re-review is required at that time.

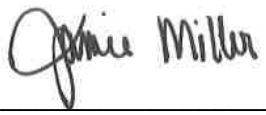
If a formulary exception is approved, H.P. Acthar Gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/29/12 |
| Revised: | 12/12/12 – Removed indication specific criter. & added "criteria for all other indications" |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, added exception statement, updated formatting |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 3/1/16 – annual review, added FA section |
| Revised: | 5/1/16 – updated format, logo, & procedure, added authorization duration indicator |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated formatting, defined EEG, removed Unicode character |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 249.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Cycloset**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cycloset for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Cycloset may be made for members who meet the following criteria:

- Medical record documentation of therapeutics failure on, intolerance to, or contraindication to three (3) oral formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Cycloset will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

metformin, glyburide, glipizide, glipizide sustained-release, chlorpropamide, glimepiride, acarbose, miglitol, repaglinide, pioglitazone, Jardiance, Synjardy, Farxiga, Xigduo XR, Tradjenta, Jentadueto, Rybelsus*

*prior authorization required

Geisinger

**POLICY NUMBER: 249.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Cycloset**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/21/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, updated formatting, updated Prandin to generic repaglinide |
| Revised: | 3/1/15 – annual review, updated signature, removed VII from alternatives, removed Byetta & Bydureon from alternatives, added Jardiance, Tanzeum & Victoza to alternatives, changed Actos to pioglitazone |
| Revised: | 3/1/16 – annual review, added Toujeo, Synjardy, Invokana, & Invokamet to FA, updated PA/ST indicator |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 250.0**

**SECTION: Commercial Drug**
**SUBJECT: Jakafi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jakafi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Jakafi may be made for members who meet the following criteria:

**For Myelofibrosis**

- Medical record documentation that Jakafi is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count greater than or equal to 50 x $10^9$/L **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of a baseline Total Symptom Score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Jakafi will not be used concurrently with Inrebic

**NOTE:** Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

✓ Age > 65 years
✓ WBC > 25 x $10^9$/L
✓ Hemoglobin < 10 g/dL

- ✓ Blood Blasts ≥ 1%
- ✓ Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- ✓ Transfusion dependency
- ✓ Platelets less than 100 X $10^9$/L
- ✓ Unfavorable karyotype

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Jakafi will no longer be covered if medical record documentation does not show:

- ✓ Medical record documentation of platelet count greater than or equal to 50 x $10^9$/L **AND**
- ✓ The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- ✓ The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

**For Polycythemia Vera**

- Medical record documentation of a diagnosis of polycythemia vera **AND**
- Medical record documentation that member requires phlebotomy **AND**
- Medical record documentation of splenomegaly **AND**
- Medical record documentation of an inadequate response or intolerance to hydroxyurea **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to interferon therapy **OR** medical record documentation of post – polycythemia vera myelofibrosis with hydroxyurea-refractory symptomatic splenomegaly **OR** severe constitutional symptoms

**AUTHORIZATION DURATION:** Initial approval will be given for 6 months or less is the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**For Graft versus Host Disease**

- Medical record documentation that Jakafi is prescribed by a hematologist/oncologist or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD) **OR**
- Medical record documentation of both of the following:
    - Documentation of a diagnosis of chronic graft-versus-host disease (cGVHD) **AND**
    - Documentation of therapeutic failure of one or two prior lines of systemic therapy

**AUTHORIZATION DURATION:** Initial approval will be given for 6 months or less is the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**Note for GVHD:** Tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. Taper will take at least 4 months. If signs/symptoms recur during or after the taper, Jakafi can be restarted.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT (all indications):** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

If a formulary exception is approved, Jakafi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

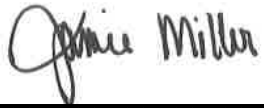
**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 250.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Jakafi |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/21/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 2/9/15 – added polycythemia vera indication |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – updated platelet count to ≥ 50 for myelofibrosis, added transfusion dependency, platelets < 100, and unfavorable karyotype to intermediate/high risk definition, corrected refractory typo, changed SV to Accredo |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, corrected 2 typos, updated prescribed criteria, added grandfather language, removed QL indicator |
| Reviewed: | 3/1/19 – annual review, defined abbr., removed Unicode characters, added QL approval note, removed distribution information |
| Revised: | 7/23/19 – added GVHD indication, indicated QL is for all indications |
| Revised: | 11/20/19 – added not to be used in combo with Inrebic for myelofibrosis |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/23/21 – added chronic GVHD indication |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

| Geisinger | POLICY NUMBER: 251.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Kalydeco** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kalydeco for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Kalydeco may be made for members who meet the following criteria:

- Medical record documentation that Kalydeco is prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of age greater than or equal to 1 month **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation of one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation per product labeling as evidenced by a Food and Drug Administration (FDA) cleared cystic fibrosis mutation test **AND**
- Medical record documentation that the patient is not homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets or granule packets per day, 30 day supply per fill

**NOTE:**

| | | | | | |
|---|---|---|---|---|---|
| *2789+5G→A* | *D110H* | *F1052V* | *G551S* | *R117H* | *S549R* |
| *3272-26A→G* | *D1152H* | *F1074L* | *K1060T* | *R347H* | *S945L* |
| *3849+10kbC→T* | *D1270N* | *G1069R* | *L206W* | *R352Q* | *S977F* |
| *711+3A→G* | *D579G* | *G1244E* | *P67L* | *R74W* | |
| *A1067T* | *E193K* | *G1349D* | *R1070Q* | *S1251N* | |
| *A455E* | *E56K* | *G178R* | *R1070W* | *S1255P* | |
| *D110E* | *E831X* | *G551D* | *R117C* | *S549N* | |

**AUTHORIZATION DURATION:** Initial authorization period will be defined at four (4) months. Re-review will occur at this time. Additional authorization will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis.

After the initial four (4) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis.

If a formulary exception is approved, Kalydeco will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 7/29/13 – updated language regarding *F508del* mutation
Reviewed: 3/1/14 – annual review
Revised: 7/22/14 – added new gene mutations, added day supply limit, removed CuraScript as preferred

| | |
|---|---|
| | vendor, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 4/13/15 – added *R117H* mutation to policy |
| Revised: | 7/22/15 – updated age to 2 years for all mutations except *R117H* |
| Revised: | 11/20/15 – removed duplicate section referencing *R117H* |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 10/3/17 – updated mutation chart |
| Revised: | 1/18/18 – updated format of prescriber & age criteria, increased auth duration to 4 months, updated signature, removed QL indicators |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 7/27/18 – added CF specialist, added per labeling to mutation crit., moved table to note |
| Revised: | 2/6/19 – updated age to 12 months, added QL note to CSR |
| Revised: | 3/1/19 – annual review, defined abbr., removed distribution information |
| Revised: | 10/1/19 – updated age to 6 months |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/26/21 – updated age to 4 months |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 7/24/23 – updated signature title; updated age to 1 month |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 252.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Korlym**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Korlym for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Korlym may be made for members who meet the following criteria:

- Medical record documentation that Korlym is prescribed by an endocrinologist **AND**
- Medical record documentation of a negative pregnancy test within 14 days of initiating Korlym therapy in women of reproductive potential **AND**
- Medical record documentation of a diagnosis of endogenous Cushing's syndrome **AND**
- Medical record documentation of failed surgical treatment for Cushing's syndrome or that the patient is not a candidate for surgery **AND**
- Medical record documentation of therapeutic failure or, contraindication to, or intolerance to conventional therapy for hyperglycemic control

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 28 day supply per fill

If a formulary exception is approved, Korlym will be paid for under the member's prescription drug benefit.

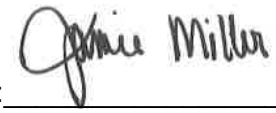
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 252.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Korlym |

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/21/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, updated formatting |
| Revised: | 3/1/16 – annual review, removed duplicate medical record documentation statement, updated CuraScript to Accredo |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, removed QL indicator, added DS limit, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note, removed distribution information |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 253.0**

**SECTION: Commercial Drug**
**SUBJECT: Orencia Subcutaneous (SC)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orencia SC for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of adult rheumatoid arthritis:**

An exception for coverage of Orencia SC may be made for members who meet the following criteria:

- Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial two (2) preferred formulary biologics for the treatment of rheumatoid arthritis
- Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

Geisinger

**POLICY NUMBER: 253.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Orencia Subcutaneous (SC)**

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on Orencia therapy is required.

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Rinvoq*, Xeljanz*

*prior authorization required

| Geisinger | POLICY NUMBER: 253.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Orencia Subcutaneous (SC) |

**For treatment of polyarticular juvenile idiopathic arthritis:**

An exception for coverage of Orencia SC may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- If Orencia ClickJect autoinjector is prescribed: Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of polyarticular juvenile idiopathic arthritis on Orencia therapy is required.

**NOTE:** The safety and efficacy of Orencia ClickJect autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

**FORMULARY ALTERNATIVES:**

Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Xeljanz*

*prior authorization required

| Geisinger | POLICY NUMBER: 253.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Orencia Subcutaneous (SC)** |

**For treatment of psoriatic arthritis:**

An exception for coverage of Orencia SC may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of two (2) preferred formulary biologics for the treatment of psoriatic arthritis **AND**
- Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- If Orencia ClickJect autoinjector is prescribed: Medical record documentation of age greater than or equal to 18 years

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriatic arthritis on Orencia therapy is required.

**NOTE:** The safety and efficacy of Orencia ClickJect autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

**FORMULARY ALTERNATIVES:**

Adult PsA: Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Otezla*, Skyrizi*, Tremfya*, Rinvoq*, Xeljanz/XR*

Pediatric PsA: Cosentyx*, Enbrel*

*prior authorization required

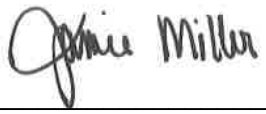
| Geisinger | POLICY NUMBER: 253.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Orencia Subcutaneous (SC)** |

If a formulary exception is approved, Orencia SC** will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| | |
|---|---|
| Devised: | 6/21/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 9/22/14 – updated diagnosis, joint count, and alternatives criteria, modified auth duration wording, updated signature and FA |
| Revised: | 2/9/15 – updated alternatives criteria and formulary alternatives |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 9/19/15 – removed joint count criteria from initial and renewal requirements |
| Revised: | 3/1/16 – annual review, removed dup. medical record statement, updated formatting |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 10/9/17 – added JIA and PsA indications |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed & age criteria, removed QL indicator, added grandfather language |
| Revised: | 5/30/18 – added combination with other biologic agents, added history of PP for PsA, removed failure of Enbrel and added failure of Cosentyx (PsA) |
| Revised: | 10/1/18 – removed failure of Enbrel & updated FA (RA) |
| Revised: | 3/1/19 – annual review, added QL approval note, defined abbr. |
| Revised: | 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 253.0**

**SECTION: Commercial Drug**
**SUBJECT: Orencia Subcutaneous (SC)**

Revised: 1/1/23 – updated all indications & FA to allow Orencia after failure of 2 preferred agents, added auth duration
Revised: 3/1/23 – annual review; removed one-time approval language due to NF status
Revised: 3/1/24 – annual review; updated signature; updated FA
Revised: 4/10/24 – updated PsA age to 2 years & added ped alts.; added ClickJet for 18 and older criterion

Geisinger

**POLICY NUMBER: 255.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xalkori**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xalkori for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xalkori may be made for members who meet the following criteria:

**Metastatic ALK-positive NSCLC**

- Medical record documentation that Xalkori is prescribed by an oncologist **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Alecensa

**Metastatic ROS1-positive NSCLC**

- Medical record documentation that Xalkori is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) that is ROS1-positive

**Anaplastic Large Cell Lymphoma (ALCL)**

- Medical record documentation that Xalkori is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK) positive **AND**
- Medical record documentation of at least one prior systemic treatment

**Inflammatory Myofibroblastic Tumor**

- Medical record documentation that Xalkori is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is anaplastic lymphoma kinase (ALK) positive

**NOTE:** The FDA approved test can be found at https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xalkori is configured as a prior authorization for new starts only. Xalkori will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Xalkori will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 255.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xalkori**

**FORMULARY ALTERNATIVES:**
Non-Small Cell Lung Cancer: Alecensa*, Zykadia*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/21/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – added ROS1-positive NSCLC |
| Revised: | 3/1/17 – annual review, updated QL to capsules |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/18 – separated indications, added failure of Alecensa for ALK+, updated prescriber criteria, updated FA, updated signature, updated QL |
| Revised: | 3/1/18 – annual review, corrected typo, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/26/21 – added ALCL indication, updated QL to 4 per day |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 10/3/22 – added myofibroflastic tumor indication, updated FDA test note & FA, corrected typo |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 256.0**

**SECTION: Commercial Drug**
**SUBJECT: Zelboraf**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zelboraf for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zelboraf may be made for members who meet the following criteria:

**Metastatic Melanoma**

- Medical record documentation that Zelboraf is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of a Food and Drug Administration (FDA)-approved test documenting the presence of the BRAF V600E mutation

**Erdheim-Chester Disease**

- Medical record documentation that Zelboraf is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of a diagnosis of Erdheim-Chester disease (ECD) **AND**
- Medical record documentation of a Food and Drug Administration (FDA)-approved test documenting the presence of the BRAF V600 mutation

**NOTE:** The FDA-approved test is the Cobas® 4800 BRAF V600 Mutation Test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Zelboraf is configured as a prior authorization for new starts only. Zelboraf will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Zelboraf will be paid for under the member's prescription drug benefit.

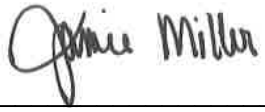
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 256.0**

**SECTION: Commercial Drug**
**SUBJECT: Zelboraf**

| | |
|---|---|
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/17 – updated prescriber criteria, separated indications, added ECD, updated QL, updated signature |
| Revised: | 3/1/18 – annual review, corrected 2 typos, added grandfather language |
| Revised: | 4/10/18 – defined FDA, updated ECD to BRAF V600 mutation |
| Revised: | 3/1/19 – annual review, defined abbr., added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; corrected typo |
| Revised: | 3/1/24 – annual review; updated signature |

| Geisinger | POLICY NUMBER: 257.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Abiraterone** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for abiraterone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of abiraterone may be made for members who meet the following criteria:

- Medical record documentation that abiraterone is prescribed by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic disease **AND**
- Medical record documentation that prednisone will be administered concomitantly with abiraterone **AND**
- Medical record documentation of one of the following:
    - That the member is no longer responding to castration or is hormone resistant **OR**
    - That the member has high-risk[†], castration-sensitive disease

[†]**NOTE:** In clinical trials, patients were considered to be high risk if they had two of the following factors at baseline: a total Gleason score of greater than or equal to 8, presence of greater than or equal to 3 lesions on bone scan, and evidence of measurable visceral metastases.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 21406010200320 & 21406010200330), number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 250 mg tablet: 4 tablets per day, 30 day supply per fill
  - 500 mg tablets: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Abiraterone is configured as a prior authorization for new starts only. Abiraterone will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, abiraterone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

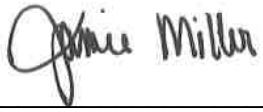
Castration Resistant Prostate Cancer: Xtandi*, Yonsa

Castration Sensitive Prostate Cancer: Xtandi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 257.0**

**SECTION: Commercial Drug**
**SUBJECT: Abiraterone**

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/21/12 |
| Revised: | 1/25/13 – Updated policy criteria |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescribed criteria, removed QL indicator, updated FA |
| Revised: | 6/1/18 – removed prednisone dosing, adding castration sensitive, added high risk note, updated QL |
| Revised: | 8/7/18 – added concomitant prednisone |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – updated policy to generic name, added one-time PA language to approval criteria, removed auth duration & added re-auth criteria |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 259.0**

**SECTION: Commercial Drug**
**SUBJECT: Pancreaze, Pertzye, Viokace, and Zenpep**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pancreaze, Pertzye, Viokace, and Zenpep for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of **Viokace** may be made for members who meet the following criteria:

- Medical record documentation of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Viokace is being prescribed in conjunction with a proton pump inhibitor **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Creon

An exception for coverage of **Pancreaze, Pertzye, and Zenpep** may be made for members who meet the following criteria:

- Medical record documentation of exocrine pancreatic insufficiency **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Creon

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Pancreaze, Pertzye, Viokace, or Zenpep will be paid for under the member's prescription drug benefit.

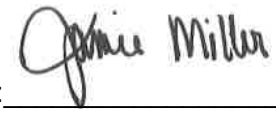
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | **POLICY NUMBER: 259.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Pancreaze, Pertzye, Viokace, and Zenpep** |

**FORMULARY ALTERNATIVES:**
pancrelipase, Creon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/18/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters, removed Ultresa (D/C by man.) |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 10/12/20 – added Pancreaze & Zenpep to policy, removed failure of Zenpep |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 262.0**

**SECTION: Commercial Drug**
**SUBJECT: Xtandi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xtandi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xtandi may be made for members who meet the following criteria:

**Castration Resistant Prostate Cancer (CRPC)**

- Medical record documentation that Xtandi is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer **AND**
- Medical record documentation that the member is no longer responding to castration or is hormone resistant **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**Non-Metastatic Castration Sensitive Prostate Cancer (nmCSPC)**

- Medical record documentation that Xtandi is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer **AND**
- Medical record documentation that the member has nonmetastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)†

†**NOTE:** In clinical trials, high risk BCR patients were defined by a PSA doubling time ≤ 9 months.

**Metastatic Castration Sensitive Prostate Cancer (mCSPC)**

- Medical record documentation that Xtandi is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer **AND**
- Medical record documentation That the member has metastatic castration-sensitive prostate cancer **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 40 mg capsules: 4 capsules per day, 30 day supply per fill
  - 40 mg tablets: 4 tablets per day, 30 day supply per fill
  - 80 mg tablets: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xtandi is configured as a prior authorization for new starts only. Xtandi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Xtandi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

abiraterone acetate*, Yonsa*, Zytiga*

*prior authorization required

Geisinger

**POLICY NUMBER: 262.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xtandi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/7/12 |
| Revised: | 1/25/13 – Added authorization duration |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 2/1/14 – updated criteria to require failure on Zytiga |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 12/1/14 – removed failure of docetaxel from criteria, updated signature |
| Revised: | 3/1/15 – annual review, added PA indicator to Zytiga |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language, removed QL indicator, updated QL to daily dose |
| Revised: | 4/10/18 – removed failure of Zytiga |
| Revised: | 10/8/18 – removed metastatic requirement, defined castration resistant, added concurrent GnRH analog or orchiectomy |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 1/28/20 – added indication for metastatic castration-sensitive prostate cancer |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, corrected abiraterone typo |
| Revised: | 6/7/21 – added QL for tablets |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 2/13/24 – updated signature title; separated indications; added nmCSPC |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 263.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Bosulif**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bosulif for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Bosulif may be made for members who meet the following criteria:

**Newly diagnosed chronic phase Ph+ CML**

- Medical record documentation that Bosulif is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)

**Chronic, accelerated, or blast phase Ph+ CML resistant or intolerant of prior therapy**

- Medical record documentation that Bosulif is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy (imatinib, Sprycel*, or Tasigna*)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 100 mg tablets: 3 tablets per day, 30 day supply per fill
  - 400 mg tablets: 1 tablet per day, 30 day supply per fill
  - 500 mg tablets: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Bosulif is configured as a prior authorization for new starts only. Bosulif will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Bosulif will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

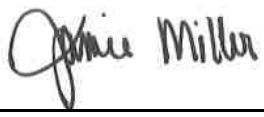
**FORMULARY ALTERNATIVES:**

imatinib, Sprycel*, Tasigna*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 263.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Bosulif**

| | |
|---|---|
| Devised: | 11/7/12 |
| Revised: | 1/25/13 – Added quantity limit and authorization duration |
| Revised: | 3/1/13 – annual review, updated logo, quantity limits, and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Gleevec to imatinib |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/18 – updated to separate indications, updated prescriber criteria, added newly diagnosed, updated QL, defined abbreviations, updated signature |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 265.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Albendazole**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for albendazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of albendazole may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (hydatid disease or neurocysticercosis)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, albendazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

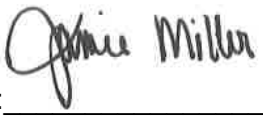
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 265.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Albendazole**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/7/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, defined FDA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Albenza to generic albendazole |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 267.0**

**SECTION: Commercial Drug**
**SUBJECT: Ivermectin Lotion (generic Sklice)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ivermectin lotion (generic Sklice) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of ivermectin lotion (generic Sklice) may be made for members who meet the following criteria:

- Medical record documentation of age less than or equal to 2 years **AND** therapeutic failure on, intolerance to, or contraindication to over the counter (OTC) permethrin **OR**
- Medical record documentation of age greater than or equal to 2 years **AND** therapeutic failure on, intolerance to, or contraindication to over the counter (OTC) permethrin **AND** over the counter (OTC) pyrethrins

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, ivermectin lotion (generic Sklice) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

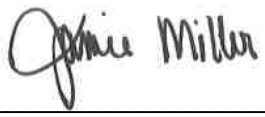
**FORMULARY ALTERNATIVES:**

lindane shampoo, malathion, spinosad

| Geisinger | POLICY NUMBER: 267.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ivermectin Lotion<br>(generic Sklice) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/7/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Sklice to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 268.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tadalafil 2.5 mg and 5 mg**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tadalafil 2.5 mg and 5 mg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).

4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
   C. In accordance with current standards of medical practice;
   D. Not primarily for the convenience of the Member, or the Member's Provider; and
   E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of tadalafil 2.5 mg or 5 mg may be made for members who meet the following criteria:

- Medical record documentation of use to treat the signs and symptoms of benign prostatic hyperplasia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to finasteride, dutasteride, alfuzosin, **AND** tamsulosin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

If an exception is made, tadalafil 2.5 mg or 5 mg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

finasteride, alfuzosin, tamsulosin, dutasteride

Geisinger

**POLICY NUMBER: 268.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tadalafil 2.5 mg and 5 mg**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/7/12 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, changed Avodart to dutasteride |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, clarified that policy only applies to 5 mg strength |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated to generic name, added note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, deleted GPID note, added 2.5 mg dose to policy |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 269.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Stivarga**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Stivarga for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Stivarga may be made for members who meet the following criteria:

**Colorectal Cancer (CRC)**

- Medical record documentation that Stivarga is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic colorectal cancer (CRC) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three prior failures which must include treatment with the following drugs:
    - fluoropyrimidine (examples are capecitabine, floxuridine, or fluorouracil (5-FU)) – based chemotherapy
    - oxaliplatin – based chemotherapy
    - irinotecan – based chemotherapy
    - an anti – VEGF therapy (bevacizumab)
    - *if* KRAS wild type, an anti-EGFR therapy (cetuximab or panitumumab)

**Gastrointestinal Stromal Tumor (GIST)**

- Medical record documentation that Stivarga is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to imatinib mesylate (Gleevec) and sunitinib malate (Sutent*)

**Hepatocellular Carcinoma**

- Medical record documentation that Stivarga is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of hepatocellular carcinoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sorafenib (Nexavar)*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 84 tablets per 28 days (4 tablets per day for 21 days of 28 day cycle)

**RE-AUTHORIZATION CRITERIA:** Stivarga is configured as a prior authorization for new starts only. Stivarga will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Stivarga will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

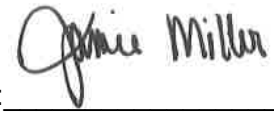
Metastatic Colorectal Cancer: capecitabine
Metastatic Gastrointestinal Stromal Tumor: imatinib, sunitinib*
Hepatocellular Carcinoma: sorafenib*

*prior authorization required

| Geisinger | **POLICY NUMBER: 269.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Stivarga** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/7/12 |
| Revised: | 1/25/13 – added authorization duration |
| Revised: | 3/1/13 – annual review, updated logo and definitions, fixed typo |
| Revised: | 6/24/13 – added GIST indication, updated formulary alternatives |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated bullet format, changed Xeloda to capecitabine |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Gleevec to imatinib |
| Revised: | 8/8/17 – added indication headers, added hepatocellular carcinoma, updated QL & FA |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 1/5/22 – updated QL to reflect appropriate dosing |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 271.0**

**SECTION: Commercial Drug**
**SUBJECT: Binosto**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Binosto for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Binosto may be made for members who meet the following criteria:

- Medical record documentation of treatment of osteoporosis in postmenopausal women **OR** treatment to increase bone mass in men with osteoporosis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to generic alternatives in tablet form: ibandronate **AND** alendronate **AND** risedronate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Binosto will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

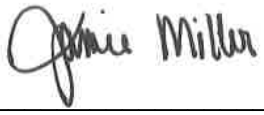
**FORMULARY ALTERNATIVES:**

alendronate, ibandronate, risedronate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 271.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Binosto** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/25/13 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added risedronate to formulary alternatives |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/27/17 – failure of risedronate |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 272.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lurasidone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lurasidone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of lurasidone may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary atypical antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole) **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ziprasidone and aripiprazole for members with metabolic syndrome

**OR**

- Medical record documentation of a diagnosis of depressive episodes associated with Bipolar I Disorder (bipolar depression) **AND**
- **For members 18 years of age or older:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, lurasidone will be paid for under the member's prescription drug benefit.

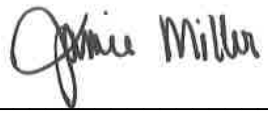
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Schizophrenia: olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole
Bipolar Depression: quetiapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/25/13 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 11/15/13 – added bipolar depression indication, updated formulary alternatives |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, changed Abilify to aripiprazole |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Revised: | 5/30/18 – updated failure of quetiapine to only if over 18 for bipolar |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Latuda to lurasidone & added generic only approval language |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 273.0**

**SECTION: Commercial Drug**
**SUBJECT: Xeljanz and Xeljanz XR**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xeljanz and Xeljanz XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***DMARD*** *– disease modifying anti-rheumatic drug*

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of rheumatoid arthritis**
An exception for coverage of Xeljanz or Xeljanz XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of adalimumab* **OR** Enbrel* **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

**NOTE:** Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. The maximum recommended dosage for rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis are Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
  - Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*

*prior authorization required

**For treatment of psoriatic arthritis**
An exception for coverage of Xeljanz or Xeljanz XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic disease modifying antirheumatic drug (DMARD) therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of adalimumab* **OR** Enbrel* **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

**NOTE:** Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. The maximum recommended dosage for rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis are Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
  - Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

**For treatment of ulcerative colitis**
An exception for coverage of Xeljanz may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of adalimumab* **AND**
- Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker, potent immunosuppressant (e.g., azathioprine and cyclosporine), or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Xeljanz 5 mg or 10 mg*: 2 tablets per day, 30 day supply per fill
  - Xeljanz XR 11 mg or 22 mg*: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

***NOTE:** Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. These dosages are not recommended for the treatment of rheumatoid arthritis and psoriatic arthritis.

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

**For treatment of polyarticular course juvenile idiopathic arthritis**
An exception for coverage of Xeljanz may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of active polyarticular course juvenile idiopathic arthritis **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Xeljanz is prescribed by a rheumatologist **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of adalimumab* **OR** Enbrel* **AND**
- Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz oral solution is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**NOTE:** Xeljanz XR is not indicated for the treatment of pcJIA. The maximum dose for pcJIA is 5 mg (tablet or solution) twice daily. Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
  - Xeljanz oral solution: 10 mL per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*

*prior authorization required

**For treatment of ankylosing spondylitis**
An exception for coverage of Xeljanz may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of adalimumab* **OR** Enbrel* **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

**NOTE:** Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. The maximum recommended dosage for rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis are Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
  - Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*

*prior authorization required

If an exception is made, Xeljanz or Xeljanz XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/25/13 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 9/22/14 – updated diagnosis, joint count, and alternatives criteria, modified auth duration wording, updated signature and FA |
| Revised: | 2/9/15 – updated alternatives criteria and formulary alternatives |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 9/19/15 – removed joint count criteria from initial and renewal requirements |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – updated existing QL, added Xeljanz XR QL |
| Revised: | 3/1/17 – annual review, added Xeljanz XR |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria |
| Revised: | 4/10/18 – added indication headers, RA (added no other biologic language), added PsA, updated FA |
| Revised: | 5/31/18 – added DMARD failure to RA, moved FA |
| Revised: | 10/1/18 – removed failure of Enbrel & updated FA (RA) |
| Revised: | 11/28/18 – added UC indication, added QL note to RA & PsA |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 01/28/20 – removed failure of Humira, added prior biologic failure, updated FA (RA) |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/4/20 – updated QL for RA/PsA to GPID, added Xeljanz XR for UC, updated UC QL & note |
| Revised: | 7/29/20 – added dosing criteria and note to RA AND PsA |

| | |
|---|---|
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, corrected typo in note |
| Revised: | 3/26/21 – added pcJIA indication |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 6/7/22 – added failure of Humira & removed failure of MTX/other biologic for RA |
| Revised: | 1/1/23 – updated to allow Xeljanz after Humira or Enbrel & FA for RA, PsA, & PJIA, added AS |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated Humira to adalimumab in criteria; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 274.0**

**SECTION: Commercial Drug**
**SUBJECT: Omeclamox**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Omeclamox for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Omeclamox may be made for members who meet the following criteria:

- Medical record documentation of a confirmed *Helicobacter pylori* infection **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a formulary proton pump inhibitor (omeprazole, pantoprazole, lansoprazole, rabeprazole) + amoxicillin + clarithromycin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Omeclamox will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole, amoxicillin, clarithromycin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 274.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Omeclamox** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/25/13 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, added rabeprazole to alternatives |
| Revised: | 3/1/16 – annual review, removed DMARD definition |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 275.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Teriflunomide 7 mg**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for teriflunomide 7 mg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of teriflunomide 7 mg may be made for members who meet the following criteria:

- Medical record documentation of why patient is unable to utilize teriflunomide 14 mg tablet once daily

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 28 day supply per fill

If an exception is made, teriflunomide 7 mg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

teriflunomide 14 mg, Avonex, Betaseron, glatiramer acetate, Extavia, fingolimod 0.5 mg, Gilenya 0.25 mg, Mayzent, Plegridy, Rebif, dimethyl fumarate

Geisinger

**POLICY NUMBER: 275.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Teriflunomide 7 mg**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/25/13 |
| Revised: | 3/1/13 – annual review, updated logo and definitions |
| Revised: | 3/1/14 – annual review, remove DMARD definition from policy |
| Revised: | 4/1/14 – updated criteria to require Gilenya & Tecfidera in addition to Copaxone & Betaseron, updated alternatives |
| Revised: | 12/1/14 – added grandfather provision, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, update formatting of policy bullets |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 1/25/17 – updated title to include 7 mg only, updated criteria for 7 mg only, added QL |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, removed note & added grandfather criteria |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated Aubagio to teriflunomide; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 276.0**

**SECTION: Commercial Drug**
**SUBJECT: Absorica**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Absorica for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Absorica may be made for members who meet the following criteria:

- Medical record documentation a diagnosis of severe nodular acne **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to conventional therapy (includes systemic antibiotics and topicals) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Claravis **AND** Myorisan

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Absorica will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Topical Therapies
adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, sulfur, topical tretinoin

Oral Therapies
doxycycline, minocycline, erythromycin, trimethoprim/sulfamethoxazole, azithromycin, isotretinoin, Claravis, Zenatane, Amnesteem

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 276.0**

**SECTION: Commercial Drug**
**SUBJECT: Absorica**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/04/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – removed failure of Amnesteem, updated FA |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 277.0**

**SECTION: Commercial Drug**
**SUBJECT: Cometriq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cometriq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Cometriq may be made for members who meet the following criteria:

- Medical record documentation that Cometriq is prescribed by an oncologist **AND**
- Medical record documentation a diagnosis of progressive metastatic medullary thyroid cancer

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 60 mg daily dose: 3 capsules per day, 28 day supply per fill
  - 100 mg daily dose: 2 capsules per day, 28 day supply per fill
  - 140 mg daily dose: 4 capsules per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Cometriq is configured as a prior authorization for new starts only. Cometriq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Cometriq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

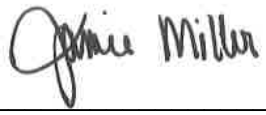
**FORMULARY ALTERNATIVES:**

Caprelsa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/4/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – added authorization duration |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria |
| Revised: | 6/1/18 – added QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 278.0**

**SECTION: Commercial Drug**
**SUBJECT: Iclusig**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Iclusig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Iclusig may be made for members who meet the following criteria:

- Medical record documentation that Iclusig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of T315I mutation positive chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)

  **OR**
  - Medical record documentation of a diagnosis of accelerated or blast phase chronic myeloid leukemia (CML) **OR** Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND**
  - Medical record documentation of resistance or intolerance to all other indicated tyrosine kinase inhibitors, including but not limited to bosutinib, dasatinib, imatinib, and nilotinib

  **OR**
  - Medical record documentation of a diagnosis of chronic phase chronic myeloid leukemia (CML) **AND**
  - Medical record documentation of resistance or intolerance to at least two prior tyrosine kinase inhibitors

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Iclusig is configured as a prior authorization for new starts only. Iclusig will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Iclusig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

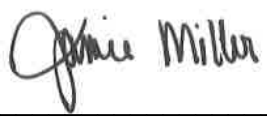
**FORMULARY ALTERNATIVES:**

imatinib, Sprycel*, Tasigna*, Bosulif*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 278.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Iclusig**

| | |
|---|---|
| Devised: | 5/4/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated formatting of authorization duration |
| Revised: | 5/1/16 – updated format, logo, & procedure, updated Gleevec to imatinib |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria |
| Revised: | 6/1/18 – added QL |
| Revised: | 8/21/18 – removed CML from T315I mutation |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/26/21 – split indication to AP/BP CML & ALL after failure of all TKI; T315I positive; CP CML after failure of 2 TKI, updated QL |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 280.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alogliptin/Pioglitazone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for alogliptin/pioglitazone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of alogliptin/pioglitazone may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta in combination with pioglitazone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, alogliptin/pioglitazone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

pioglitazone, metformin, Tradjenta, Jentadueto, Jentadueto XR

Geisinger

**POLICY NUMBER: 280.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alogliptin/Pioglitazone**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/24/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated PA requirements to ST |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Oseni to alogliptin/pioglitazone |
| Revised: | 11/28/17 – removed indication, added failure of Tradjenta & QL, updated FA/signature |
| Revised: | 2/9/18 – removed failure of sitagliptin, updated FA |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note, removed ST indicator from FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 281.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Pomalyst**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pomalyst for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Pomalyst may be made for members who meet the following criteria:

**Multiple Myeloma**

- Medical record documentation that Pomalyst is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of multiple myeloma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies: bortezomib (Velcade*) and lenalidomide (Revlimid*) **AND**
- Medical record documentation that Pomalyst is being prescribed in combination with dexamethasone **OR** medical record documentation that the patient is steroid intolerant

**Kaposi Sarcoma**

- Medical record documentation that Pomalyst is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of Kaposi sarcoma **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of AIDS-related Kaposi sarcoma **AND**

- Medical record documentation of progression of Kaposi sarcoma despite the use of antiretroviral therapy **AND**
- Medical record documentation that antiretroviral therapy will be continued

**OR**

- Medical record documentation that the member is HIV-negative

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 21 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Pomalyst is configured as a prior authorization for new starts only. Pomalyst will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Pomalyst will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

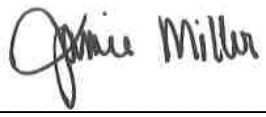
Multiple Myeloma: lenalidomide*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 281.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Pomalyst** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/24/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 7/22/15 – added steroid requirement |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, removed QL indicator |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – added Kaposi sarcoma indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature, updated FA |

Geisinger

**POLICY NUMBER: 283.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Everolimus (generic Zortress)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for everolimus (generic Zortress) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of everolimus (generic Zortress) may be made for members who meet the following criteria:

**Kidney Transplant**

- Medical record documentation that everolimus (generic Zortress) is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation that member received a kidney transplant **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Everolimus (generic Zortress) is being administered in combination with basiliximab (Simulect) induction and concurrently with reduced doses of cyclosporine and corticosteroids **OR**
    - Medical record documentation that member has had a prior therapeutic failure on, intolerance to, or contraindication to calcineurin inhibitors

**Liver Transplant**

- Medical record documentation that everolimus (generic Zortress) is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation that member received a liver transplant **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation that everolimus (generic Zortress) is being administered no earlier than 30 days post-transplant **AND**
- Medical record documentation of one of the following:
    - Everolimus (generic Zortress) is being administered in combination with low-dose tacrolimus and corticosteroids **OR**
    - Medical record documentation that member has had a prior therapeutic failure on, intolerance to, or contraindication to calcineurin inhibitors

**NOTE:**

- Everolimus (generic Zortress) (and other mTOR inhibitors) should not be administered any sooner than 30 days after liver transplant due to risk of hepatic artery thrombosis in the early post-transplantation period.
- The use of corticosteroids beyond the first week post-transplant is controversial and varies between treatment centers. The 2009 KDIGO guidelines recommend for kidney transplant patients at low immunogenic risk and who receive induction therapy, to discontinue prednisone during the first week post-transplant.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, everolimus (generic Zortress) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Renal Transplant: azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus, sirolimus solution*, sirolimus tablets*

Liver Transplant: cyclosporine, mycophenolate mofetil, tacrolimus

*prior authorization required

Geisinger

**POLICY NUMBER: 283.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Everolimus (generic Zortress)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/24/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, added Rapamune Solution & sirolimus tabs |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated format of prescriber, age, and diagnosis criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/21/19 – added failure of calcineurin inhibitors, added note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated to generic |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 284.0**

**SECTION: Commercial Drug**
**SUBJECT: Deferasirox**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for deferasirox for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of deferasirox may be made for members who meet the following criteria:

**Chronic Iron Overload caused by Transfusion-Dependent Thalassemia**

- Medical record documentation of a diagnosis of chronic iron overload caused by transfusion dependent thalassemia **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a serum ferritin level greater than 1,000 mcg/L

**Chronic Iron Overload caused by Non-Transfusion Dependent Thalassemia**

- Medical record documentation of a diagnosis of chronic iron overload caused by non-transfusion dependent thalassemia **AND**
- Medical record documentation of age greater than or equal to 10 years **AND**
- Medical record documentation of liver iron concentration (LIC) greater than 5 mg Fe/g dw **AND**
- Medical record documentation of serum ferritin greater than 300 mcg/L

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

**AUTHORIZATION DURATION:** If approved, initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level greater than 300 mcg/L.

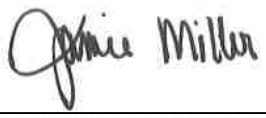
If an exception is made, deferasirox will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/24/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, updated authorization duration format |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 6/2/17 – added Jadenu to policy, auth duration to 6 months, reauth ferritin to >300 |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria |
| Revised: | 10/8/18 – removed caused by Transfusion-Dependent Thalassemia from chronic iron overload indication and updated re-auth to ferritin > 500 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Exjade to generic deferasirox |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Jadenu to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 285.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Icatibant**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for icatibant for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of icatibant may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that icatibant is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of hereditary angioedema supported by physician documentation of
    - Recurrent, self-limiting non-inflammatory subcutaneous angioedema without urticarial, lasting more than 12 hours **OR**
    - Laryngeal edema **OR**
    - Recurrent, self-remitting abdominal pain lasting more than 6 hours, without clear organic etiology **AND**
    - The presence of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticarial **AND**
- Medication is being used as a treatment of acute hereditary angioedema attack **AND**
- Physician provided documentation of concurrent use of failure on, intolerance to, or contraindication to prophylactic therapy (androgen)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. Quantities requested above limits will be reviewed for necessity. Exceptions will be allowed for patients maximizing prophylactic therapies and medical record documentation of acute attacks requiring more than 3 syringes monthly.*

- QL FOR LETTER ONLY: 3 syringes (9 mL) per 30 days

| Geisinger | POLICY NUMBER: 285.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Icatibant |

**AUTHORIZATION DURATION:** Initial authorization with be for 6 months, with annual review thereafter. Icatibant will no longer be covered if patient is no longer using prophylactic therapy and does not have medical record documentation of contraindication or intolerance to all prophylactic therapy options.

If an exception is made, icatibant will be paid for under the member's prescription drug benefit.

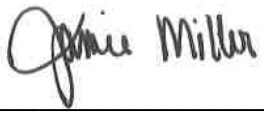
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, corrected typo in authorization duration |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria, removed QL indicator |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Firazyr to generic icatibant |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |

Geisinger

**POLICY NUMBER: 285.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Icatibant**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 286.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Gattex**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gattex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Gattex may be made for members who meet the following criteria:

- Medical record documentation that Gattex is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of short bowel syndrome **AND**
- If age 1 to 17 years:
  - Medical record documentation that the member is dependent on parenteral nutrition/intravenous support at least 3 times per week
- If age greater than or equal to 18 years:
  - Medical record documentation that the member has been dependent on parenteral nutrition/intravenous support for a minimum of 12 consecutive months continuously **AND**
  - Medical record documentation that the member requires concurrent parenteral nutrition at least three days per week

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: One (1) vial per day, 30 day supply limit per fill

**AUTHORIZATION DURATION:** If approved, approval will be for an initial duration of six (6) months. For continuation of coverage, medical record documentation of a decrease of at least 20% volume of parenteral nutrition/intravenous support from baseline is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of sustained improvements in the volume of parenteral nutrition/intravenous support that the member requires while on Gattex therapy.

If an exception is made, Gattex will be paid for under the member's prescription drug benefit.

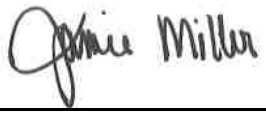
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, corrected typo in authorization |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria, removed QL indicator |
| Reviewed: | 3/1/19 – annual review, added QL approval note, updated QL to match package size |
| Revised: | 10/1/19 – updated age to 1 year |
| Revised: | 11/20/19 – revised parenteral nutrition requirements and separated by age |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 287.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Mytesi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mytesi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Mytesi may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) **AND**
- Medical record documentation of antiretroviral therapy for at least four (4) week duration **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on loperamide **AND** diphenoxylate-atropine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Mytesi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

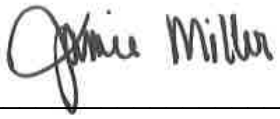
**FORMULARY ALTERNATIVES:**

loperamide, diphenoxylate-atropine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 287.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Mytesi** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, added loperamide and diphenoxylate-atropine to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, corrected typo |
| Revised: | 11/29/17 – updated drug name to Mytesi, updated signature |
| Revised: | 3/1/18 – annual review, removed QL indicator, defined HIV/AIDS, updated Fulyzaq to Mytesi, corrected typo |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 288.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Signifor**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Signifor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Signifor may be made for members who meet the following criteria:

- Medical record documentation that Signifor is prescribed by endocrinology **AND**
- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ketoconazole **AND** metyrapone*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 60 ampules per month, for each strength

**AUTHORIZATION DURATION:** If approved, approval will be given for a period of six (6) months. Re-authorization will require medical record documentation that urinary free cortisol levels are within normal limits.

If an exception is made, Signifor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

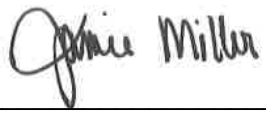
| Geisinger | POLICY NUMBER: 288.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Signifor |

**FORMULARY ALTERNATIVES:**
ketoconazole, metyrapone*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, corrected typo in authorization duration |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber/diagnosis criteria, removed QL indicator |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 290.0**

**SECTION: Commercial Drug**
**SUBJECT: Ravicti**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ravicti for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ravicti may be made for members who meet the following criteria:

- Medical record documentation of a urea cycle disorder **AND**
- Medical record documentation of a protein-restricted diet **AND**
- Medical record documentation of increased blood ammonia levels **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on sodium phenylbutyrate powder* or Buphenyl powder* **AND** Buphenyl tablet*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 19 gm (17.3 mL) per day

**AUTHORIZATION DURATION:** Initial authorization will be for 6 months of therapy. Re-review will be annually thereafter. Ravicti will no longer be covered if the patient does not show improvement in either fasting ammonia levels, 24-hour AUC, or number of hyperammonemic crises.

If an exception is made, Ravicti will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

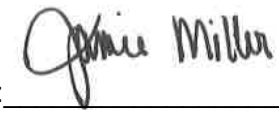
| Geisinger | POLICY NUMBER: 290.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ravicti |

**FORMULARY ALTERNATIVES:**
sodium phenylbutyrate powder*, Buphenyl Tablet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, corrected typo in authorization duration |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/3/17 – updated age from 2 years to 2 months |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria, corrected typo |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 5/24/19 – removed age requirement |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 292.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Erlotinib**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for erlotinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of erlotinib may be made for members who meet the following criteria:

**Non-Small Cell Lung Cancer**

- Medical record documentation that erlotinib is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer **AND**
- Medical record documentation that erlotinib is being used as first line treatment **OR** maintenance treatment **OR** second line or greater treatment after progression on at least one prior chemotherapy regimen **AND**
- Medical record documentation of one of the following epidermal growth factor receptor (EGFR) mutations as detected by a Food and Drug Administration (FDA) approved test
    - Exon 19 deletion
    - Exon 21 (L858R) substitution

**Pancreatic Cancer**

- Medical record documentation that erlotinib is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced, unresectable, or metastatic pancreatic cancer **AND**

- Medical record documentation of erlotinib being prescribed in combination with gemcitabine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 100 mg and 150 mg tablets: 1 tablet per day, 30 day supply per fill
  - 25 mg tablets: 3 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Erlotinib is configured as a prior authorization for new starts only. Erlotinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, erlotinib will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

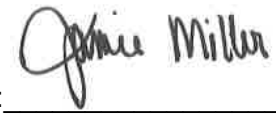
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 292.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Erlotinib** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, corrected typo in authorization duration |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/27/17 – updated NSCLC indication, increased auth duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, corrected 2 typos, updated prescriber criteria, added grandfather language, updated format/added DS limit |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Tarceva to generic erlotinib |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 293.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Juxtapid**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Juxtapid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Juxtapid may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND** either
  - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
  - Diagnosis made based on history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

  **AND**
- Medical record documentation that Juxtapid is prescribed by a hepatologist, lipidologist, or cardiologist registered with the Juxtapid risk evaluation and mitigation strategies (REMS) program **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and ezetimibe defined as:
  - Greater than or equal to 100 mg/dL in patients without cardiovascular disease
  - Greater than or equal to 70 mg/dL in patients with established cardiovascular disease

  **AND**
- Medical record documentation of Juxtapid to be used in adjunct with maximum tolerated statin dose **AND** low density lipoprotein (LDL) apheresis **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor **AND**
- If the request is for use in combination with Evkeeza: Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with a minimum 3-month trial of Evkeeza without the concomitant use of Juxtapid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 5 mg and 10 mg capsules: 1 capsule per day, 28 day supply per fill
  - 20 mg and 30 mg capsules: 2 capsules per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be granted for a period of six (6) months. A new prior authorization may be submitted at that time for continuation of therapy. Subsequent approval will be for one (1) year and will require medical record documentation that current medical necessity criteria are met and that therapy has been effective.

If an exception is made, Juxtapid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin, simvastatin, ezetimibe, rosuvastatin, Repatha*, Praluent*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 293.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Juxtapid** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/29/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature, updated procedure to Juxtapid |
| Revised: | 7/22/15 – updated QL |
| Revised: | 3/1/16 – annual review, corrected typo in authorization duration, added failure of Repatha, added Repatha to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – updated Crestor to rosuvastatin |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber/age criteria, removed QL indicator, updated FA, corrected typo |
| Revised: | 3/1/19 – annual review, added QL approval note, defined abbr. |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 9/1/21 – updated LDL failure levels, removed failure of Kynamro, updated Repatha criteria to allow any PCSK9, added Evkeeza criteria, updated QL, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 4/6/22 – updated diag. reqs., removed failure of apheresis & Repatha, added failure of ezetimibe |
| Revised: | 3/1/23 – annual review; corrected typo |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 294.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zolmitriptan Nasal Spray**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for zolmitriptan nasal spray for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 296.0 Triptan Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of zolmitriptan nasal spray may be made for members who meet the following criteria:

- Medical record documentation of a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sumatriptan nasal spray for patients 18 years of age and older **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rizatriptan **AND** almotriptan for patients 12 to 18 years or age

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 16 units per 28 days (The quantity limit of 16 units per 28 days applies to each individual nasal or injectable product however applies *across all triptan oral tablet products.) (*1 unit = 1 tablet = 1 injection = 1 nasal spray)

If an exception is made zolmitriptan nasal spray will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 294.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zolmitriptan Nasal Spray**

**FORMULARY ALTERNATIVES:**

sumatriptan**, Cafergot, rizatriptan**, rizatriptan tablet dispersible**, Migranal, DHE 45, naratriptan**

** quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/13 |
| Revised: | 3/1/14 – annual review, corrected typo |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 1/20/15 – added age indicator to alternatives, added ages 12-18 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, defined FDA, removed QL indicator |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Zomig to generic, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 295.0**

**SECTION: Commercial Drug**
**SUBJECT: Almotriptan, Eletriptan, and Frovatriptan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for almotriptan, eletriptan, and frovatriptan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 296.0 Triptan Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of almotriptan, eletriptan, or frovatriptan may be made for members who meet the following criteria:

- Medical record documentation of a medically accepted indication:
    - Almotriptan, eletriptan, frovatriptan: migraine
    - Frovatriptan: short term menstrual related migraines

**AND**

- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment

**AND**

- Based on indication:
    - **For migraine indication**: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sumatriptan, naratriptan, and rizatriptan **OR**
    - **For short term menstrual related migraines:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication naratriptan **OR**
    - **For members 12-17 years with migraines (almotriptan only):** medical record documentation of therapeutic failure, intolerance to, or contraindication to rizatriptan and sumatriptan

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 16 doses per 28 days (Dose limit applies across all triptan products.)

If an exception is made, almotriptan, eletriptan or frovatriptan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

sumatriptan**, Cafergot, rizatriptan**, Migranal, DHE 45, naratriptan**

** Quantity Limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Axert & Frova to almotriptan & frovatriptan |
| Revised: | 3/1/18 – annual review, updated signature & Relpax to generic, removed QL indicator |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated QL to indicate it applies across all triptans |
| Revised: | 3/1/24 – annual review; updated signature; updated to generic only auth entry |

Geisinger

**POLICY NUMBER: 296.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Triptan Quantity Limit Exception**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for triptan quantity limit exceptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for the quantity limit of 16 units in 28 days of a triptan product may be made for members who meet the following criteria. (NOTE: Dose limit applies across all ORAL triptan products):

- Medical record documentation that requested medication is prescribed by a neurologist **AND**
- The greater than 16 dose per month prescription is being used for a medically accepted indication, including:
  - Cluster Headaches
  - Headache Bridging
  - Menstrual Migraine

**AND**

- Member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of current use of prophylaxis therapy or therapeutic failure, contraindication, or intolerance to **ALL** of the following:
  - Beta blocker (metoprolol, propranolol, atenolol, nadolol or timolol)
  - Topiramate
  - Amitriptyline
  - Divalproex or Sodium Valproate
  - Venlafaxine

If the QL exception is made for headache bridging therapy only a one month prior authorization override will be provided. Future need for a triptan headache bridge will require additional prior authorization.

*1 unit = 1 tablet = 1 injection = 1 nasal spray. The quantity limit of 16 units per 28 days applies across all triptan products.

| Geisinger | POLICY NUMBER: 296.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Triptan Quantity Limit Exception** |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

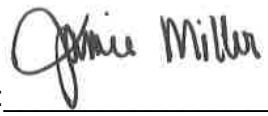
If an exception is made, the triptan quantity limit exception will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, removed Unicode |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated QL to reflect applicability across all triptans |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 297.0**

**SECTION: Commercial Drug**
**SUBJECT: Sirturo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sirturo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Sirturo may be made for members who meet the following criteria:

- Medical record documentation Sirturo is prescribed by a physician specializing in infectious disease **AND**
- Medical record documentation of one of the following:
  - Age greater than or equal to 18 years **OR**
  - Age greater than or equal to 5 years, weighing at least 15 kilograms **AND**
- Medical record documentation of resistance to isoniazid **AND** rifampin **AND**
- Medical record documentation that an effective treatment regimen cannot be attained with other available treatment options **AND**
- Medical record documentation of one of the following:
  - Sirturo is being prescribed in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible to in vitro **OR**
  - If in vitro testing results are unavailable, Sirturo is being prescribed in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- 100 mg tablets: First Fill – 56 tablets, Subsequent Fills – 24 tablets
- 20 mg tablets: First Fill – 280 tablets, Subsequent Fills – 120 tablets

**AUTHORIZATION DURATION:** 24 weeks

If an exception is made, Sirturo will be paid for under the member's prescription drug benefit.

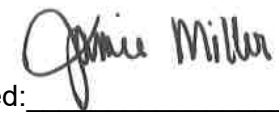
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

amoxicillin-clavulanic acid, clarithromycin, ethambutol, isoniazid, levofloxacin, pyrazinamide, rifampin, moxifloxacin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/7/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, corrected typo in auth duration, changed Avelox to moxifloxacin |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, defined MDR-TB |
| Revised: | 1/28/20 – updated for new indication in patients 12 to less that 18 years weighing at least 30 kg and added criteria for when in vitro testing results are unavailable |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/18/20 – Changed age from 12 years/30 kg to 5 years/15 kg, added 20 mg tablet QL |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; defined kg |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 298.0**

**SECTION: Commercial Drug**
**SUBJECT: Osphena**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Osphena for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Osphena may be made for members who meet the following criteria:

**Severe Vaginal Dryness**

- Medical record documentation of a diagnosis of menopause **AND**
- Medical record documentation that the member is experiencing moderate to severe vaginal dryness, a symptom of vulvar vaginal atrophy, due to menopause **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an over the counter (OTC) vaginal moisturizer and/or lubricant **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary topical estradiol/ conjugated estrogen products (e.g., cream, tablet, ring)

**NOTE:** Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause is excluded from coverage, except for certain clients that request this benefit (treatment of female sexual dysfunction).

**Dyspareunia**

- Medical record documentation of a diagnosis of menopause **AND**
- Medical record documentation that the member is experiencing at least one of the following symptoms of vulvar and vaginal atrophy:
  - Moderate to severe dyspareunia
  - Moderate to severe vaginal dryness **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an over the counter (OTC) vaginal moisturizer and/or lubricant **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary topical estradiol/ conjugated estrogen products (for example, cream, tablet, ring)

**QUANTITY LIMIT:** 1 tablet per day

If an exception is made, Osphena will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
Premarin Vaginal Cream, Estring, estradiol vaginal cream, Yuvafem

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/07/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Vagifem to Yuvafem |
| Retired: | 2/20/18 |
| Reinstated: | 7/23/19 |
| Revised: | 8/1/19 – removed duplicate criteria, corrected typo |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed TPA reference from exclusions
Revised: 3/1/23 – annual review; defined abbreviations
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 304.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tafinlar and Mekinist**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tafinlar and Mekinist for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tafinlar or Mekinist may be made for members who meet the following criteria:

**Unresectable or Metastatic Melanoma**

- Medical record documentation that Tafinlar or Mekinist is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600E or V600K mutations as detected by a Food and Drug Administration (FDA)-approved test **AND**
- One of the following:
    - Medical record documentation that the requested medication is being used as a single agent **AND**
    - If the request is for Mekinist as a single agent: Medical record documentation of no prior therapeutic failure with a BRAF inhibitor therapy (e.g., Zelboraf, Tafinlar, or Braftovi)
      **OR**
    - Medical record documentation that Mekinist and Tafinlar will be used in combination

**Metastatic Non-Small Cell Lung Cancer**

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test

**Adjuvant Treatment of Melanoma**

- Medical record documentation that Tafinlar and Mekinist are prescribed by a dermatologist, hematologist, or oncologist **AND**
- Medical record documentation of melanoma with involvement of lymph node(s) **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E or V600K mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Mekinist and Tafinlar will be used as adjuvant treatment following complete resection

**Anaplastic Thyroid Cancer**

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced or metastatic anaplastic thyroid cancer **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test

**Unresectable or Metastatic Solid Tumors**

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E mutation **AND**
- Medical record documentation of previous treatment resulting in disease progression

**Low-Grade Glioma (LGG)**

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to one year and less than 18 years **AND**
- Medical record documentation of low-grade glioma (LGG) **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E mutation **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tafinlar: 4 capsules per day, 30 day supply per fill
  - Tafinlar Tablets for Oral Suspension: 30 tablets per day, 30 day supply per fill
  - Mekinist 1 mg and 2 mg: 1 tablet per day, 30 day supply per fill
  - Mekinist 0.5 mg: 3 tablets per day, 30 day supply per fill
  - Mekinist for Oral Solution: 40 mL per day, 30 day supply per fill

**NOTE TO CSR:**

- If the request is for metastatic non-small cell lung cancer, adjuvant treatment of melanoma, or anaplastic thyroid carcinoma, enter two (2) authorizations, one (1) for Mekinist and one (1) for Tafinlar with appropriate authorization durations and quantity limits.
- If the request is for unresectable or metastatic melanoma **OR** unresectable or metastatic solid tumors as combination therapy (Mekinist and Tafinlar), enter two (2) authorizations, one (1) for Mekinist and one (1) for Tafinlar with appropriate authorization durations and quantity limits.
- If the request is for unresectable or metastatic melanoma as a single agent, enter an authorization for the requested medication with appropriate authorization duration and quantity limits.

**AUTHORIZATION DURATION (for Adjuvant Treatment of Melanoma):** Approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The FDA-approved treatment duration is for 12 months only. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

**AUTHORIZATION DURATION (for all other indications):** Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Tafinlar and/or Mekinist will no longer be covered if there is medical record documentation of disease progression.

If an exception is made, Tafinlar and/or Mekinist will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

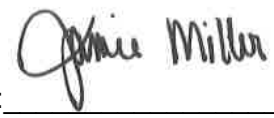
**FORMULARY ALTERNATIVES:**

Unresectable or Metastatic Melanoma: Zelboraf*, Braftovi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 304.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tafinlar and Mekinist**

| | |
|---|---|
| Devised: | 10/7/13 |
| Revised: | 3/1/14 – annual review, added PA indicator for Zelboraf |
| Revised: | 3/20/14 – added criteria regarding concomitant use with Mekinist |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/9/17 – removed no prior therapy from melanoma, added NSCLC, auth to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, removed QL indicator |
| Revised: | 8/21/18 – combined Mekinist/Tafinlar policies for unresectable or metastatic melanoma and metastatic NSCLC, added adjuvant treatment of melanoma and thyroid cancer indications, added note to CSR, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 10/3/22 – added unresectable or metastatic solid tumors indication |
| Revised: | 3/1/23 – annual review; added Mekinist to all other indication auth duration |
| Revised: | 6/5/23 – updated signature title; added LGG indication; added QL for oral suspension/solution |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 305.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Topiramate XR (generic Trokendi XR)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for topiramate XR (generic Trokendi XR) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of topiramate XR (generic Trokendi XR) may be made for members who meet the following criteria:

**Seizure Disorders**

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut Syndrome **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topiramate extended release sprinkle capsules (generic Qudexy XR)*

**Migraine Headache Prophylaxis**

- Medical record documentation of use for prophylaxis of migraine headaches **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topiramate extended release sprinkle capsules (generic Qudexy XR)*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, topiramate XR (generic Trokendi XR) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

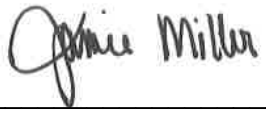
**Seizure Disorders**: carbamazepine, divalproex, felbamate, valproic acid, topiramate immediate release, topiramate extended release*, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, zonisamide, gabapentin, tiagabine, phenobarbital, Lyrica

**Migraine Prophylaxis**: topiramate immediate release, topiramate extended release*, propranolol, timolol, divalproex delayed release, divalproex extended release, amitriptyline, atenolol, metoprolol, nadolol, venlafaxine, sodium valproate

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/15/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 4/13/15 – added indication and age requirements
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 11/22/16 – updated FA
Reviewed: 3/1/17 – annual review
Revised: 6/2/17 – added migraine, updated seizures to trial of topiramate ER, updated FA

| | |
|---|---|
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Trokendi to topiramate |
| Revised: | 3/1/24 – annual review; updated signature; clarified failure is of generic Qudexy |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 306.0**

**SECTION: Commercial Drug**
**SUBJECT: Procysbi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Procysbi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Procysbi may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of nephropathic cystinosis **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation that Procysbi is prescribed by a nephrologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of intolerance to Cystagon and one of the following:
        - If intolerance is gastrointestinal-related, medical record documentation of therapeutic failure on 4 months of Cystagon and a proton-pump inhibitor (for example, omeprazole, esomeprazole) **OR**
        - If intolerance is not gastrointestinal-related, justification supported by peer-review literature citing well-designed clinical trials that the member's intolerance will be improved by switching therapy to Procysbi

      **OR**
    - Medical record documentation of therapeutic failure on Cystagon as defined by all of the following:
        - Medical record documentation of failure to achieve white blood cell (WBC) cystine levels less than 1 nmol half-cystine/mg protein on maximally tolerated dose of Cystagon **AND**
        - Claims history or attestation from the provider that the patient is adherent to Cystagon at an every 6 hour dosing interval

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**DAY SUPPLY LIMIT:** 34 day supply per fill

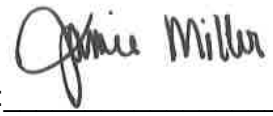
If an exception is made, Procysbi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
Cystagon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/15/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 1/29/16 – updated age from 6 years to 2 years |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, removed QL indicator |
| Revised: | 5/30/18 – updated age to 1 year |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – defined intolerance and failure to Cystagon |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 307.0**

**SECTION: Commercial Drug**
**SUBJECT: Gilotrif**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gilotrif for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Gilotrif may be made for members who meet the following criteria:

- Medical record documentation that Gilotrif is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of first line treatment for metastatic non-small cell lung cancer (NSCLC) with tumors that have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by a Food and Drug Administration (FDA) approved test **OR**
- Medical record documentation of a diagnosis of metastatic, squamous non-small cell lung cancer (NSCLC) which has progressed after platinum-based chemotherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill for each strength

**RE-AUTHORIZATION CRITERIA:** Gilotrif is configured as a prior authorization for new starts only. Gilotrif will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Gilotrif will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

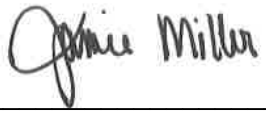
**FORMULARY ALTERNATIVES:**

erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/15/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – added metastatic NSCLC which has progressed after platinum based therapy
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, removed QL indicator

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 307.0**

**SECTION: Commercial Drug**
**SUBJECT: Gilotrif**

Revised: 4/6/18 – removed second line treatment and updated EGFR requirements
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Tarceva to generic
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 309.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Trintellix**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trintellix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Trintellix may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Major Depressive Disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) antidepressant classes

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Trintellix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 309.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Trintellix |

**FORMULARY ALTERNATIVES:**

**SSRIs:** citalopram, fluoxetine, paroxetine, sertraline, escitalopram
**MAOIs:** phenelzine, tranylcypromine
**SNRIs:** venlafaxine hcl, venlafaxine er, duloxetine, desvenlafaxine ER (generic Pristiq)
**Tricyclics:** amitriptyline, nortriptyline, desipramine, doxepin, imipramine
**Bupropion:** bupropion hcl, bupropion xl, bupropion sr
**Other:** trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/15/13 |
| Revised: | 3/1/14 – annual review, added duloxetine to formulary alternatives |
| Revised: | 3/1/15 – annual review, updated signature, added escitalopram to alternatives |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – updated name to Trintellix |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & FA, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 310.0**

**SECTION: Commercial Drug**
**SUBJECT: Rivastigmine Patch**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for rivastigmine patch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of rivastigmine patch may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of mild to moderate dementia of the Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to rivastigmine capsules **AND** donepezil tablets **AND** galantamine tablets

**OR**

- Medical record documentation of a diagnosis of severe dementia of the Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to donepezil tablets

**OR**

- Medical record documentation of a diagnosis of mild to moderate dementia associated with Parkinson's disease **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to rivastigmine capsules

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, rivastigmine patch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Mild to Moderate Dementia of the Alzheimer's Type:** rivastigmine capsules, donepezil tablets, galantamine tablets
**Severe Dementia of the Alzheimer's Type:** donepezil tablets
**Mild to Moderate Dementia associated with Parkinson's disease:** rivastigmine capsules

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/15/13 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated Exelon to rivastigmine |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 311.0**

**SECTION: Commercial Drug**
**SUBJECT: Sucraid**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sucraid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Sucraid may be made for members who meet the following criteria:

- Medical record documentation that Sucraid is prescribed by a gastroenterologist, endocrinologist, or genetic specialist **AND**
- Medical record documentation of a diagnosis of congenital sucrose-isomaltase deficiency characterized by stool pH less than 6 **AND**
- Medical record documentation of an increase in breath hydrogen of greater than 10 ppm when challenged with sucrose after fasting **AND**
- Medical record documentation of a negative lactose breath test **OR**
- Medical record documentation of a diagnosis of congenital sucrose-isomaltase deficiency characterized by low sucrose activity on duodenal biopsy **AND**
- Other disaccharidases normal on same duodenal biopsy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 box (two 118 mL bottles) per fill

If an exception is made, Sucraid will be paid for under the member's prescription drug benefit.

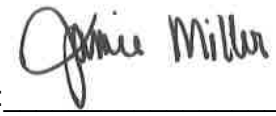
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 311.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Sucraid |

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/01/14 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 12/9/14 – changed AND in 4th bullet to OR as per P&T approved minutes, updated sig. |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, removed QL indicator |
| Revised: | 3/1/19 – annual review, added QL approval note, removed distribution information |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 312.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Brimonidine Gel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for brimonidine gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of brimonidine gel may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of persistent (non-transient) facial erythema of rosacea **AND**
- Medical record documentation of age greater than or equal to 18 years

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: One (30 gram) tube per fill

If an exception is made, Mirvaso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

metronidazole cream, metronidazole gel, metronidazole lotion, azelaic acid gel, ivermectin cream

| Geisinger | POLICY NUMBER: 312.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Brimonidine Gel |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/1/14 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, removed QL indicator |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 6/8/21 – removed failure of metronidazole, updated indication |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature; updated auth entry to generic only |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 313.0**

**SECTION: Commercial Drug**
**SUBJECT: Topical Tazarotene**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Arazlo, Fabior foam, tazarotene foam, Tazorac cream, and Tazorac gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Arazlo, Fabior foam, tazarotene foam, Tazorac cream, or Tazorac gel may be made for members who meet the following criteria:

**Acne Vulgaris (All Except Arazlo)**

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult-onset acne **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, two of which must be adapalene and tretinoin

**Acne Vulgaris (Arazlo Only)**

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult-onset acne **AND**
- Medical record documentation of age greater than or equal to 9 years **AND**
- For members 12 years of age and older: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, two of which must be adapalene and tretinoin

**Psoriasis (Tazorac 0.05% cream, Tazorac 0.05% gel and Tazorac 0.1% gel)**

- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a topical corticosteroid **OR**
  - Medical record documentation of disease involving crucial body areas such as the hands, feet, or genitals **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary alternative **AND** at least 2 to 3 months of methotrexate or phototherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for tazarotene foam add generic only

If an exception is made, Arazlo, Fabior foam, tazarotene foam, Tazorac cream, or Tazorac gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Acne: adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin*

*prior authorization required for members over the age of 30

Psoriasis:

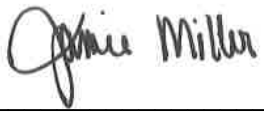
- Cyclosporine, methotrexate, tacrolimus ointment
- Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
- Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
- High-potency topical corticosteroids: amcinonide 0.1% cream, ointment and lotion Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate

0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

- Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/1/14 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 3/1/16 – annual review, removed Differin 0.3% gel from FA, added tretinoin microsphere gel to FA, removed 0.1% from adapalene FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 10/6/22 – added tazarotene foam, Tazorac gel/cream, & Arazlo; added Arazlo & PsO criteria; updated all other acne therapeutic alt criterion |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; added generic only for tazarotene foam |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 314.0**

**SECTION: Commercial Drug**
**SUBJECT: Tobramycin Inhalation Solution (generic Bethkis)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined tobramycin inhalation solution (generic Bethkis) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of tobramycin inhalation solution (generic Bethkis) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that tobramycin inhalation solution (generic Bethkis) is prescribed by a pulmonologist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 224 mL per 56 days

If an exception is made, tobramycin inhalation solution (generic Bethkis) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

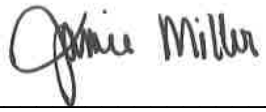
tobramycin inhalation solution*, Tobi inhalation solution*, Tobi PodHaler*

*prior authorization required

| Geisinger | POLICY NUMBER: 314.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tobramycin Inhalation Solution (generic Bethkis) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/1/14 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 11/20/15 – removed failure of tobramycin nebules |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, removed AND from last bullet |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, removed QL indicator |
| Revised: | 3/1/19 – annual review, added QL approval note, added PA indicator to FA |
| Revised: | 6/4/19 – removed CSR QL note, added authorization parameters |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Bethkis to generic, updated QL/auth parameter statements |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated auth entry to generic only |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 315.0**

**SECTION: Commercial Drug**
**SUBJECT: Imbruvica**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Imbruvica for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Imbruvica may be made for members who meet the following criteria:

**Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) **OR** small lymphocytic lymphoma (SLL)

**Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with 17p deletion**

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) with 17p deletion **OR** small lymphocytic lymphoma with 17p deletion

**Waldenström's macroglobulinemia**

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of Waldenström's macroglobulinemia

**Chronic Graft Versus Host Disease (cGVHD)**

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of chronic graft versus host disease **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of therapeutic failure on one or more lines of systemic therapy **AND**
- Medical record documentation that the member is receiving an appropriate dose** based on the age and body surface area (BSA)

****NOTE:** Recommended dosage for cGVHD:
Patients 12 years of age and older: 420mg orally once daily
Pediatric patients 1 to less than 12 years of age to achieve 240 mg/m$^2$ orally once daily:

| BSA(m$^2$) Range | Dose (mg) of Imbruvica Capsules/Tablets to Administer | Dose of Imbruvica Oral Suspension (70 mg/mL) to Administer |
|---|---|---|
| >0.3 to 0.4 | - | 84mg OR 1.2mL |
| >0.4 to 0.5 | - | 105mg OR1.5mL |
| >0.5 to 0.6 | - | 133mg OR 1.9mL |
| >0.6 to 0.7 | - | 154mg OR 2.2mL |
| >0.7 to 0.8 | 210mg | 182mg OR 2.6mL |
| >0.8 to 0.9 | 210mg | 203mg OR 2.9mL |
| >0.9 to 1.0 | 210mg | 231mg OR 3.3mL |
| >1.0 to 1.1 | 280mg | 252mg OR 3.6mL |
| >1.1 to 1.2 | 280mg | 280mg OR 4.0mL |
| >1.2 to 1.3 | 280mg | 301mg OR 4.3mL |
| >1.3 to 1.4 | 350mg | 322mg OR 4.6mL |
| >1.4 to 1.5 | 350mg | 350mg OR 5.0mL |
| >1.5 to 1.6 | 350mg | 371mg OR 5.3mL |
| >1.6 | 420mg | 420mg OR 6.0mL |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tablets/Capsules: 1 tablet or capsule per day, 28 day supply per fill
  - Oral Suspension: 6 mL per day, 36 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Imbruvica is configured as a prior authorization for new starts only. Imbruvica will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Imbruvica will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Mantle Cell Lymphoma: Brukinsa*, Calquence*, Revlimid*
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Calquence*, Venclexta*
Chronic Graft Versus Host Disease: prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, sirolimus, Jakafi*, imatinib

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/1/14
Reviewed: 3/1/14 – annual review

| | |
|---|---|
| Revised: | 3/20/14 – added CLL indication |
| Revised: | 9/22/14 – added CLL 17p deletion indication, clarified that Revlimid is alter. for MCL |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 4/13/15 – added Waldenström's macroglobulinemia, added indication headers |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/22/16 – added SLL indication, removed failure of prior therapy for CLL/SLL |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/6/17 – corrected typo in lymphocytic |
| Revised: | 3/27/17 – added marginal zone lymphoma, increased auth duration to 12 months |
| Revised: | 10/10/17 – added cGVHD, updated FA |
| Revised: | 3/1/18 – annual review, updated signature & prescriber language, added grandfather language, updated format of indication headers, removed QL indicator |
| Revised: | 4/6/18 – updated all QL to 1 per day, 28 day supply per fill |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 2/04/20 – updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/19/23 – updated cGVHD age to 1 year; added cGVHD note; added suspension QL |
| Revised: | 3/1/23 – annual review; corrected typo |
| Revised: | 7/25/23 – removed mantle cell & marginal zone lymphoma indications; updated signature title |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 316.0**

**SECTION: Commercial Drug**
**SUBJECT: Fetzima**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fetzima for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fetzima may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three antidepressant classes, one of which must be a generic serotonin and norepinephrine reuptake inhibitor (SNRI)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

If an exception is made, Fetzima will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

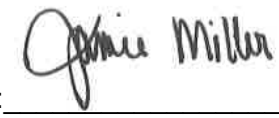
| Geisinger | POLICY NUMBER: 316.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Fetzima |

**FORMULARY ALTERNATIVES:**

**Selective Serotonin Reuptake Inhibitors (SSRIs):** citalopram, fluoxetine, paroxetine, sertraline, escitalopram
**Monoamine Oxidase Inhibitors (MAOIs):** phenelzine, tranylcypromine
**Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs):** duloxetine, venlafaxine hcl, venlafaxine er, desvenlafaxine ER (generic Pristiq)
**Tricyclics:** amitriptyline, nortriptyline, desipramine, doxepin, imipramine
**Bupropion:** bupropion hcl, bupropion xl, bupropion sr
**Other:** trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/1/14 |
| Reviewed: | 3/1/14 – annual review |
| Revised: | 7/22/14 – corrected typo, updated signature |
| Revised: | 3/1/15 – annual review, added escitalopram to alternatives |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature & FA, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 317.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Valchlor**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Valchlor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Valchlor may be made for members who meet the following criteria:

- Medical record documentation that Valchlor is prescribed by a dermatologist or oncologist **AND**
- Medical record documentation of first a diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one of the following skin-directed therapies: topical corticosteroid, topical retinoid, topical nitrogen mustard, phototherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Each authorization will be for 12 months. Re-review will occur every 12 months. Valchlor will no longer be covered if there is medical record documentation of disease progression.

If an exception is made, Valchlor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

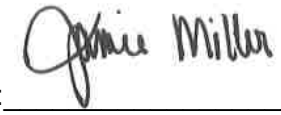
**Topical Retinoids**: Targretin*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 317.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Valchlor** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/1/14 |
| Revised: | 3/1/14 – annual review, corrected typo |
| Revised: | 3/1/15 – annual review, updated signature |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language |
| Revised: | 3/1/19 – annual review, removed distribution information |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 318.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Stelara**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Stelara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Stelara may be made for members who meet the following criteria:

**Psoriasis**

- Medical record documentation that Stelara is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to or therapeutic failure on a minimum 3 month trial of four (4) preferred formulary biologics for the treatment of psoriasis **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**NOTE:**

- Patients weighing over 100 kg should receive 90 mg every 12 weeks
- Patients weighing less than 100 kg should receive 45 mg every 12 weeks

**RE-AUTHORIZATION CRITERIA:** Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT –** *Two authorizations must be entered.*

- Stelara 45 mg syringe (less than 100 kg)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 0.5, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
    2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 0.5 mL per 28 days; Maintenance dose: 0.5 mL per 84 days
- Stelara 90 mg syringe (greater than or equal to 100 kg)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 1, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
    2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

**FORMULARY ALTERNATIVES:**

Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Otezla*, Skyrizi*, Tremfya*, Cimzia*, Ilumya*, Siliq*

*prior authorization required

**Pediatric Plaque Psoriasis**

- Medical record documentation that Stelara is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two topical corticosteroids **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**NOTE:**

- Patients weighing over 100 kg should receive 90 mg every 12 weeks
- Patients weighing ≥ 60 kg to < 100 kg should receive 45 mg every 12 weeks
- Patients weighing less than 60 kg should receive 0.75 mg/kg every 12 weeks

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT –** *Two authorizations must be entered.*

- Stelara 45 mg vial (less than 60 kg)
  1. In PA Hub: Add Treat as "Include" Process Modifier, DS, min day supply 28, max day supply 28, max quantity dispensed 1, and number of claims authorized 1, with a duration of 3 weeks.
  2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
     - QL FOR LETTER: Loading dose: 1 vial per 28 days; Maintenance dose: 1 vial per 84 days
- Stelara 45 mg syringe (less than 100 kg)
  1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 0.5, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.

2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
    - QL FOR LETTER: Loading dose: 0.5 mL per 28 days; Maintenance dose: 0.5 mL per 84 days

- Stelara 90 mg syringe (greater than or equal to 100 kg)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 1, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
    2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

**FORMULARY ALTERNATIVES:**

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05%

ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**Psoriatic Arthritis**

- Medical record documentation that Stelara is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of an intolerance to, contraindication to or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of psoriatic arthritis **AND**
- Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks **OR** medical record documentation that the patients has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weight greater than 100 kg **OR** member is under the age of 18 years and is receiving the recommended weight based dose **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**NOTES:**

- FDA approved dose for adult psoriatic arthritis is 45 mg every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dose is 90 mg every 12 weeks.
- Pediatric dosing:

| Body Weight at Time of Dosing | Recommended Dose |
|---|---|
| Less than 60 kg | 0.75 mg/kg |
| 60kg or more | 45mg |
| Greater than 100kg with co-existent moderate-to-severe plaque psoriasis | 90mg |

- Pediatric PsA is a category of juvenile idiopathic arthritis (JIA).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT –** *Two authorizations must be entered.*

- Stelara 45 mg syringe (less than 100 kg)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 0.5, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
    2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 0.5 mL per 28 days; Maintenance dose: 0.5 mL per 84 days
- Stelara 90 mg syringe (greater than or equal to 100 kg)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 1, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
    2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
        - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

**FORMULARY ALTERNATIVES:**

Adult PsA: Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Otezla*, Skyrizi*, Tremfya*, Rinvoq*, Xeljanz/XR*, Cimzia*, Orencia*, Simponi*

Pediatric PsA: Cosentyx*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*

*prior authorization required

**Crohn's Disease**

- Medical record documentation that Stelara is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active Crohn's disease **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab*, or Tysabri* **AND**
- Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) **OR** Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:**

- **Initial Approval –** *Two authorizations must be entered.*
    1. In PA Hub: Add Treat as "Include" Process Modifier, number of claims authorized 1, enter for the remainder of the calendar year
    2. In Darwin: Add DS, min day supply 56, max day supply 56, with an end date of 12/31/2099
        - QL FOR LETTER: 1 mL per 56 days

**NOTE:** Stelara 45 mg syringe is not indicated for use in Crohn's disease.

**NOTE:** If the initial infusion will be billed through the pharmacy benefit (i.e., specialty pharmacy trying to process the 130 mg/26 mL intravenous solution), in Darwin enter PA, OQL, DS only by GPI 52504070002020, enter 1 in the max number of claims authorized, max quantity 104, min and max day supply 56) with a duration of 1 month. This will be in addition to the authorization above. Also, you will need to update the QL for the letter to the following:

- QL FOR LETTER: Intravenous loading dose: 104 mL per 56 days; 90 mg Syringe maintenance dose: 1 mL per 56 days

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Cimzia*, Entyvio*, infliximab*, Tysabri*

*prior authorization required

**Ulcerative Colitis**

- Medical record documentation that Stelara is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Entyvio* **AND** infliximab* **AND**
- Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) **OR** Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**RE-AUTHORIZATION CRITERIA:** Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:**

- **Initial Approval –** *Two authorizations must be entered.*
    1. In PA Hub: Add Treat as “Include” Process Modifier, number of claims authorized 1, enter for the remainder of the calendar year
    2. In Darwin: Add DS, min day supply 56, max day supply 56, with an end date of 12/31/2099
        - QL FOR LETTER: 1 mL per 56 days

**NOTE:** Stelara 45 mg syringe is not indicated for use in ulcerative colitis.

**NOTE:** If the initial infusion will be billed through the pharmacy benefit (i.e., specialty pharmacy trying to process the 130 mg/26 mL intravenous solution), in Darwin enter PA, OQL, DS only by GPI 52504070002020, enter 1 in the max number of claims authorized, max quantity 104, min and max day supply 56) with a duration of 1 month. This will be in addition to the authorization above. Also, you will need to update the QL for the letter to the following:

- QL FOR LETTER: Intravenous loading dose: 104 mL per 56 days; 90 mg Syringe maintenance dose: 1 mL per 56 days

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Rinvoq*, Simponi*, Xeljanz/XR*

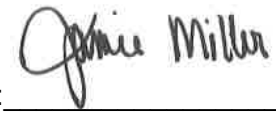
*prior authorization required

If an exception is made, Stelara will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 9/22/14 – updated alternatives criteria and auth duration for both indications, updated FA and signature, and added "at least" to age criteria for both indications
Revised: 2/9/15 – updated alternatives criteria & FA for both indications, updated prescriber criteria for PsA
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/27/16 – added dosing requirement for both indications, added dosing note
Reviewed: 3/1/17 – annual review
Revised: 3/27/17 – added Crohn's, moved notes to indication in policy

| | |
|---|---|
| Revised: | 6/2/17 – removed Unicode characters, corrected typo in Crohn's note |
| Revised: | 9/15/17 – updated Crohn's to failure of 3 agents, added induction/maintenance bullet to match P&T approved policy |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber & age criteria, added grandfather language |
| Revised: | 5/30/18 – added pediatric psoriasis, moved FA, added no use with other biologics, removed failure of Enbrel and added failure of Cosentyx (PP, PsA), added QL (PP, PsA), updated GPID note |
| Revised: | 3/1/19 – annual review, defined TNF |
| Revised: | 6/4/19 – updated QL, removed RX counts, added authorization parameters |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 4/21/20 – updated CD QL, removed reference to Remicade/Inflectra, added UC indication |
| Revised: | 1/25/21 – updated pedPP to age 6 & auth duration/QL language, added MediSpan approval level |
| Revised: | 3/1/21 – annual review, updated logo, updated QL statements, add FA to CD & UC |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO |
| Reviewed: | 1/5/22 – added OUP to all auths, updated GPI for CD 7 UC |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered |
| Revised: | 4/6/22 – updated vial QL for ped. PsO, added IV loading dose note to CD & UC |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives in pediatric PsO section |
| Revised: | 1/1/23 – updated PsO & FA to allow Stelara after failure of 4 preferred agents; updated PsA to include peds, failure of 3 preferred agents & FA; updated UC & FA to allow Stelara after failure of 3 preferred pharmacy benefit alternatives |
| Revised: | 1/19/23 – corrected age typo for PsA |
| Revised: | 3/1/23 – annual review; updated look back to 105 days |
| Revised: | 3/1/24 – annual review; updated signature; updated auth entry parameters, updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 321.0**

**SECTION: Commercial Drug**
**SUBJECT: Actemra Self-Injectable**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Actemra self-injectable for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Actemra Self Injectable may be made for members who meet the following criteria:

**Rheumatoid Arthritis**

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of rheumatoid arthritis **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Rinvoq*, Xeljanz*

*prior authorization required

**Active polyarticular juvenile idiopathic arthritis (PJIA)**

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Xeljanz*

*prior authorization required

**Active systemic juvenile idiopathic arthritis (SJIA)**

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of active systemic juvenile idiopathic arthritis **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

none

**Giant Cell Arteritis**

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of giant cell arteritis **AND**
- Medical record documentation that Actemra is being prescribed in combination with oral glucocorticoids **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**NOTE:** Although traditionally the erythrocyte sedimentation rate and/or C-reactive protein are high in giant cell arteritis, the range of values for both test is broad and non-specific.

**FORMULARY ALTERNATIVES:**

none

**Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)**

- Medical record documentation that Actemra Self Injectable is prescribed by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
- Medical record documentation of systemic sclerosis related to interstitial lung disease confirmed by all of the following:
  - greater than or equal to 10% fibrosis on a chest high resolution computer tomography **AND**
  - forced viral capacity (FVC) greater than or equal to 40% of predicted normal **AND**
  - DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

***NOTE:** ACR/EULAR Diagnostic Criteria for Systemic Sclerosis:

| Item | Sub-item(s) | Weight/score† |
|---|---|---|
| Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints *(sufficient criterion)* | – | 9 |
| Skin thickening of the fingers *(only count the higher score)* | Puffy fingers | 2 |
| | Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints) | 4 |
| Fingertip lesions *(only count the higher score)* | Digital tip ulcers | 2 |
| | Fingertip pitting scars | 3 |
| Telangiectasia | – | 2 |
| Abnormal nailfold capillaries | – | 2 |
| Pulmonary arterial hypertension and/or interstitial lung disease *(maximum score is 2)* | Pulmonary arterial hypertension | 2 |
| | Interstitial lung disease | 2 |
| Raynaud's phenomenon | – | 3 |
| SSc-related autoantibodies (anticentromere, anti–topoisomerase I [anti–Scl-70], anti–RNA polymerase III) *(maximum score is 3)* | Anticentromere<br>Anti–topoisomerase I<br>Anti–RNA polymerase III | 3 |

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).
† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥9 are classified as having definite SSc.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

none

**COVID-19**

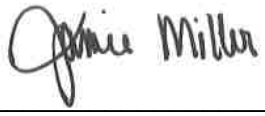
If Actemra is being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA authorized use. At this time, Actemra is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

If an exception is made, Actemra Self Injectable will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/20/14 |
| Revised: | 9/22/14 – updated joint count and alternatives criteria, added Cimzia and removed Enbrel from FA, changed auth. duration wording, and updated signature |
| Revised: | 2/9/15 – updated alternatives criteria and added Enbrel and removed Cimzia from FA |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 9/19/15 – removed joint count criteria from initial and renewal requirements |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode Characters |
| Revised: | 10/9/17 – added GCA |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age and prescriber criteria |
| Revised: | 10/1/18 – removed failure on Enbrel, updated RA FA, added PJIA indication |
| Revised: | 3/1/19 – annual review, added QL approval note, defined TNF |
| Revised: | 3/21/19 – added SJIA indication, added other biologic criteria to PJIA/GCA, updated QL's to mL |
| Revised: | 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 9/1/21 – added SSc-ILD indication |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, added COVID-19 |
| Revised: | 1/1/23 – updated to allow Actemra after failure of 2 preferred agents & FA for RA & PJIA |

Revised: 3/1/23 – annual review; defined abbreviations
Revised: 3/1/24 – annual review; updated signature; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 322.0**

**SECTION: Commercial Drug**
**SUBJECT: Fycompa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fycompa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fycompa may be made for members who meet the following criteria:

**Partial Onset Seizures**

- Medical record documentation of a diagnosis of partial onset seizures **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**Primary Generalized Tonic-Clonic Seizures**

- Medical record documentation of a diagnosis of primary generalized tonic-clonic seizures **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives **AND**
- Medical record documentation that Fycompa is being used concomitantly with at least one (1) other formulary antiepileptic drug

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Fycompa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Partial Onset Seizures**:
For patients > 4 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER*

Additional formulary alternatives for patients over certain ages:
divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

**Primary Generalized Tonic-Clonic Seizures**: carbamazepine, lamotrigine, levetiracetam, phenytoin, primidone, topiramate

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 322.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Fycompa**

| | |
|---|---|
| Devised: | 3/20/14 |
| Revised: | 3/1/15 – annual review, updated signature |
| Revised: | 9/19/15 – added primary generalized tonic-clonic seizures, updated FA |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 11/27/17 – separated indications, removed adjunct. from partial onset, updated age formatting, updated signature |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 12/27/18 – updated partial-onset seizure age and FA |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/15/19 – updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 323.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Opsumit**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Opsumit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Opsumit may be made for members who meet the following criteria:

- Medical record documentation that Opsumit is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of World Health Organization (WHO) functional class II, III, or IV pulmonary arterial hypertension **AND**
- Medical record documentation of a negative pregnancy test in females of childbearing potential **AND**
- Medical record documentation that Opsumit will be used in combination with (or therapeutic failure on, intolerance to, or contraindication to) sildenafil*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

If an exception is made, Opsumit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 323.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Opsumit |

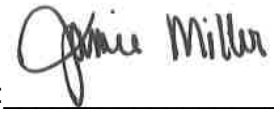
**FORMULARY ALTERNATIVES:**

Uptravi*, Orenitram*, treprostinil * (generic Remodulin), Tyvaso*, Ventavis*, Adempas*, bosentan*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/20/14 |
| Revised: | 9/22/2014 – removed failure of Tracleer & added failure of Letairis, removed Tracleer from FA, updated signature |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/22/16 – removed failure of Letairis, updated FA |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, corrected typo |
| Revised: | 3/1/19 – annual review, added QL approval note, updated QL to match package size |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review, updated signature; updated FA |

Geisinger

**POLICY NUMBER: 326.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sovaldi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sovaldi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***HCV –*** Hepatitis C Virus
7. ***FDA –*** Food and Drug Administration
8. ***HIV –*** Human Immunodeficiency Virus
9. ***HBV –*** Hepatitis B Virus

**PROCEDURE:**

An exception for coverage of Sovaldi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years using weight-based dosing **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of Hepatitis C Virus (HCV) genotype 1, 2, 3, or 4 infection in adults **OR** HCV genotype 2 or 3 in pediatric patients greater than or equal to 3 years of age, without cirrhosis or with compensated cirrhosis, as a component of a combination antiviral treatment regimen **AND**
- Medical record documentation of METAVIR liver scoring or cirrhosis assessment by a non-invasive test **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**

- Medical record documentation of receiving the following within the past 6 months:
  - Hepatic function panel
  - Complete blood count including differential
  - Basic metabolic panel **AND**
- Medical record documentation of receiving the following within a reasonable timeframe:
  - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of weight-based ribavirin, if indicated **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver-related co-morbid conditions **AND**
- Medical record documentation of completed:
  - Hepatitis B immunization series **OR**
  - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
    - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
    - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
  - Is being treated for human immunodeficiency virus (HIV) **OR**
  - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**NOTES:**

1. Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).
2. The AASLD/IDSA Guidelines only recommend single-agent sofosbuvir, in combination with other appropriate agents, for HCV infection (all genotypes) in limited situations.
3. Guidelines can be referenced at www.hcvguidlines.org.

**TREATMENT DURATION:** Consistent with AASLD/ISDA Guidelines

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 200 mg and 400 mg tablets: 1 tablet per day, 28 day supply per fill
  - 150 mg pellets: 1 packet per day, 28 day supply per fill
  - 200 mg pellets: 2 packets per day, 28 day supply per fill

**APPROVAL LANGUAGE:** Meets criteria, auth x (?) weeks, RX count= (?), (28 day supply/fill), generic only [when applicable]. QL: 1 tab/day (QL for LETTER only)

If an exception is made, Sovaldi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

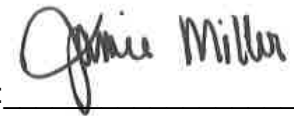
| Geisinger | POLICY NUMBER: 326.0 |
|---|---|
| POLICY AND PROCEDURE<br>PHARMACY<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Sovaldi |

**FORMULARY ALTERNATIVES (if applicable):**
Mavyret*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/28/14
Revised: 9/22/14 – Updated the following: F3/F4 fibrosis for all genotypes, abstinence from alcohol and illegal substances for all members, removed verbal commitment to therapy, life expectancy
Revised: 12/1/14 – Updated life expectance criteria to include “due to non-liver-related co-morbid conditions”
Revised: 2/9/15 – added METAVIR scoring, no S/S of decompensated liver disease, UDS, renal function
Revised: 2/16/15 – removed duplicate renal function criteria
Reviewed: 3/1/15 – annual review
Revised: 1/29/16 – added HBV/HIV to definitions, added hepatocellular screening criterion, added severe extrahepatic manifestations of hep C criterion, removed in writing from member commitment
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed no S/S of decompensated liver disease
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – updated reauthorization criteria, added “if cirrhotic” for G3, added Daklinza and noncirrhotic for G3
Revised: 11/22/16 – Added F2 fibrosis, referral to substance use treatment. Removed 6 months abstinence, substance use treatment compliance, UDS/fill history, GHP representative. Update FA, added if applicable.
Revised: 3/1/17 – annual review, defined abbreviations, removed Unicode characters
Revised: 3/27/17 – G3: removed peginterferon, added w/ Daklinza for post transplant
Revised: 6/2/17 – removed fibrosis/liver manifestations requirement, added METAVIR scoring, updated diagnosis (removed HCC and HIV co-infection), removed peginterferon references for G1 therapy, added regimen supported by

compendia, removed failure of same DAA
Revised: 8/8/17 – updated age to include 12 or older OR weight greater than 35 kg for G2 & G3, added concurrent therapy with peg/rib for G1 & concurrent therapy with rib for G3
Revised: 11/27/17 – added failure of Mavyret, updated FA, updated signature
Revised: 1/19/18 – corrected typo, removed prescriber, added Hep B & HIV criteria, updated FA
Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS, corrected typo
Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
Revised: 3/1/19 – annual review, added QL approval note, defined abbr., removed Olysio references (D/C)
Revised: 7/23/19 – added TPA COE exclusion
Revised: 01/28/20 – updated age to 3 and weight based dosing, updated genotypes, removed concurrent peginterferon criteria, updated treatment duration to consistent with AASLD/ISDA guidelines and removed subsequent authorization criteria
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/29/20 – added QL for pellets
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed St. Lukes & Atlanticare from COE note
Reviewed: 3/1/23 – annual review
Revised: 7/25/23 – removed renal impairment criterion; updated diagnosis criterion, METAVIR scoring criterion, baseline labs within 6 months, HCV RNA within reasonable timeframe, notes, signature title, authorization duration; added approval language; moved/updated ribavirin criterion
Revised: 11/1/23 – updated 400 mg pellet QL to 150 mg pellets
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 327.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aptiom**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aptiom for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Aptiom may be made for members who meet the following criteria:

- Medical record documentation that Aptiom is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to 3 formulary alternatives, one of which must be oxcarbazepine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 600 mg or 800 mg tablet: 2 tablets per day
  - 200 mg or 400 mg: 1 tablet per day

If an exception is made, Aptiom will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 327.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Aptiom** |

**FORMULARY ALTERNATIVES:**

For patients > 4 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER*

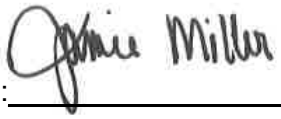
Additional formulary alternatives for patients over certain ages:

divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/28/14 |
| Revised: | 7/22/14 – removed HCV and FDA definitions |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 11/20/15 – removed adjunctive therapy requirement |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 11/22/16 – updated 800 mg QL to 2/day |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 11/27/17 – revised prescriber bullet, updated to age 4, added failure of oxcarbazepine, updated signature |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 8/7/18 – updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/15/19 – updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 329.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tasimelteon Capsules and Hetlioz LQ Suspension**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tasimelteon capsules and Hetlioz LQ suspension for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of tasimelteon capsules or Hetlioz LQ suspension may be made for members who meet the following criteria:

**Non-24-Hour Sleep-Wake Disorder (Free-Running Disorder)**

- Medical record documentation of a diagnosis of Non-24-Hour Sleep-Wake Disorder (Free-Running Disorder) **AND**
- Medical record documentation that the member is totally blind with no perception of light **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 6 months of melatonin therapy

**Smith-Magenis Syndrome (SMS)**

- Medical record documentation of a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) **AND**
- Medical record documentation of age greater than or equal to 3 years

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for tasimelteon capsules add generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Capsule: 1 capsule per day, 30 day supply per fill
  - Suspension: 5 mL per day, 30 day supply per fill

If an exception is made, tasimelteon capsules and Hetlioz LQ suspension will be paid for under the member's prescription drug benefit.

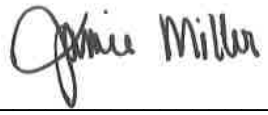
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated QL to match package size |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 6/7/21 – added SMS indication, added suspension QL |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated capsules to generic only |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 330.0**

**SECTION: Commercial Drug**
**SUBJECT: Zykadia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zykadia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zykadia may be made for members who meet the following criteria:

- Medical record documentation that Zykadia is prescribed by an oncologist **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Alecensa*

**NOTE:** The FDA approved test is the Vysis ALK Break-Apart FISH probe Kit

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Zykadia is configured as a prior authorization for new starts only. Zykadia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Zykadia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

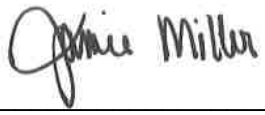
**FORMULARY ALTERNATIVES:**

Alecensa*, Xalkori*, Alunbrig*

*prior authorization and quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 8/8/17 – removed failure of Xalkori, updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 330.0**

**SECTION: Commercial Drug**
**SUBJECT: Zykadia**

| | |
|---|---|
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/18 – updated presc. criteria, updated QL, added failure of Alecensa, updated sig |
| Revised: | 3/1/18– annual review, added grandfather language, defined FDA |
| Revised: | 4/10/18 – updated QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated from capsules to tablets |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 331.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Duavee**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Duavee for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Duavee may be made for members who meet the following criteria:

- Medical record documentation of use for abnormal vasomotor function **OR** for prevention of postmenopausal osteoporosis **AND**
- Medical record documentation of age less than 75 years **AND**
- Medical record documentation of an intact uterus **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Duavee will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

clomiphene citrate, estradiol, estradiol norethindrone acetate, estropipate, norethindrone acetate/ethinyl estradiol, Combipatch, Estring, Premarin, Premphase, Prempro, estradiol patch, raloxifene, alendronate, ibandronate, risedronate

| Geisinger | POLICY NUMBER: 331.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Duavee |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, age criteria, and FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 332.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Adempas**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adempas for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Adempas may be made for members who meet the following criteria:

- Medical record documentation that Adempas is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**
- Medical record documentation of World Health Organization (WHO) functional class II, III, or IV symptoms **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of chronic thromboembolic pulmonary hypertension (CTEPH) (World Health Organization Group 4), which is inoperable or previously treated surgically **OR**
    - All of the following:
        - Medical record documentation of a diagnosis of World Health Organization (WHO) Group I pulmonary arterial hypertension **AND**
        - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with bosentan*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 30 day supply per fill

If an exception is made, Adempas will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 332.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Adempas |

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

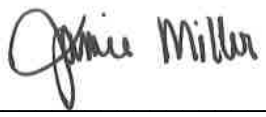
**FORMULARY ALTERNATIVES:**

Uptravi*, Orenitram*, treprostinil * (generic Remodulin), Tyvaso*, Ventavis*, Opsumit*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), bosentan*, Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/14 |
| Revised: | 9/22/14 – removed failure of Tracleer, removed Tracleer from formulary alternatives |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – revised criteria to include separate criteria for WHO group I, updated FA |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed criteria, corrected typo, updated QL to match package size |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated format, updated Tracleer to bosentan in criteria |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 333.0**

**SECTION: Commercial Drug**
**SUBJECT: Xerese**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xerese for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xerese may be made for members who meet the following criteria:

**Members 12 Years of Age and Older**

- Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Abreva (OTC), acyclovir cream*, penciclovir cream*, famciclovir **AND** valacyclovir

**Members Aged 6 to Less Than 12 Years**

- Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) **AND**
- Medical record documentation of age greater than or equal to 6 years and less than 12 years

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Xerese will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 333.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xerese |

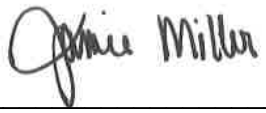
**FORMULARY ALTERNATIVES:**

acyclovir cream*, penciclovir cream*, famciclovir, valacyclovir

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated format of diagnosis/age criteria |
| Revised: | 3/1/19 – annual review, updated Zovirax to acyclovir |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated age headers\ |
| Revised: | 3/1/23 – annual review; updated Denavir to penciclovir |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 334.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Luliconazole**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for luliconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of luliconazole may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis or tinea pedis, tinea cruris, or tinea corporis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clotrimazole, econazole, ketoconazole, over the counter terbinafine, over the counter tolnaftate, **AND** over the counter miconazole **OR**
- If member is between the ages of 12 and less than 18 years: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clotrimazole, over the counter terbinafine, over the counter tolnaftate, **AND** over the counter miconazole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**AUTHORIZATION DURATION:** 2 weeks

If an exception is made, luliconazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

topical clotrimazole, topical econazole, topical ketoconazole

| Geisinger | POLICY NUMBER: 334.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Luliconazole |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 8/7/18 – updated age to 12 years, added FA for 12-18 years, added auth duration |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – updated from Luzu to generic luliconazole |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 335.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Orenitram**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orenitram for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Orenitram may be made for members who meet the following criteria:

- Medical record documentation that Orenitram is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of World Health Organization (WHO) Group 1 pulmonary arterial hypertension **AND**
- Medical record documentation of World Health Organization (WHO) functional class II or III symptoms **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Uptravi

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** 34 day supply per fill

**AUTHORIZATION DURATION:** If approved, Orenitram will require reauthorization every 6 months. At that point, the following criteria should apply:

- Medical record documentation of a 6-minute walking distance improved from baseline

If an exception is made, Orenitram will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

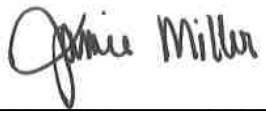
**FORMULARY ALTERNATIVES:**

Uptravi*, bosentan*, treprostinil injection*, Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, tadalafil*, sildenafil*, Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/27/16 – added failure of Uptravi, updated FA |
| Revised: | 3/1/17 – annual review, defined abbreviations, corrected typo |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria, corrected typo, moved failure of Uptravi from re-auth to initial review |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 4/21/20 – removed not in use with endothelin receptor antagonist criteria, updated FA to generics |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 336.0**

**SECTION: Commercial Drug**
**SUBJECT: Otezla**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Otezla for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Otezla may be made for members who meet **ALL** of the following criteria:

**For Psoriatic Arthritis:**

- Medical record documentation that Otezla is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
- For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Otezla is configured as a prior authorization for new starts only. Otezla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For Plaque Psoriasis:**

- Medical record documentation that Otezla is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- For mild disease:
    - Medical record documentation of a diagnosis of mild to moderate plaque psoriasis characterized by less than 5% of body surface area involved **AND**
    - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of 2 topical therapies (one of which is a corticosteroid of at least medium potency) **AND**
    - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of phototherapy
- For moderate-severe disease:
    - Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Otezla is configured as a prior authorization for new starts only. Otezla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

cyclosporine, methotrexate

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**For Behçet's Disease**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of oral ulcers associated with Behçet's Disease

**NOTE:** The International Clinical Criteria for Behçet's Disease diagnostic criteria:

- Recurrent oral ulcerations (apthous or herpetiform) at least three times in one year.
- Additionally, patients must present with two of the following:
  - Recurrent genital ulcerations
  - Eye lesions (uveitis and retinal vasculitis) observed by an ophthalmologist
  - Skin lesions (erythema nodosum, pseudofolliculitis, papulopustular lesions, acneiform nodules) found in adult patients not being treated with corticosteroids
  - Positive "pathergy test" read by a physician within 24-48 hours of testing

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Otezla is configured as a prior authorization for new starts only. Otezla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

none

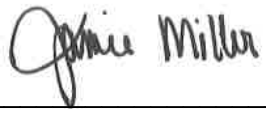
If an exception is made, Otezla will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | **POLICY NUMBER: 336.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Otezla** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/22/14 |
| Revised: | 11/21/14 – Added criteria for PsO, updated formulary alternatives |
| Revised: | 2/9/15 – Updated alternat. criteria & FA for both indications, prescriber criteria for PsA |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 9/19/15 – removed joint count criteria from initial requirements |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed & age criteria, added grandfather language, updated QL to daily dose/package size |
| Revised: | 5/30/18 – removed failure of Enbrel, added failure of Cosentyx, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/20/19 – added Behçet's Disease indication to policy |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & added QL to PsA indication |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, added FA for PsO |
| Revised: | 6/7/22 – added mild PsO criteria |
| Revised: | 1/1/23 – updated PsO & PsA FA to allow Otezla as initial biologic after failure of 1st line therapy for mod/severe disease |
| Revised: | 3/1/23 – annual review; corrected typo |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 337.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aveed**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aveed for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Aveed may be made for members who meet **ALL** of the following criteria:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
  - Primary hypogonadism (congenital or acquired)
  - Hypogonadotropic hypogonadism (congenital or acquired) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to testosterone cypionate **AND** testosterone enanthate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Aveed will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

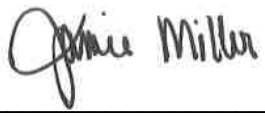
**FORMULARY ALTERNATIVES:**

testosterone cypionate, testosterone enanthate

| Geisinger | POLICY NUMBER: 337.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Aveed |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 338.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Myalept**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Myalept for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Myalept may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Myalept is prescribed by an endocrinologist **AND**
- Medical record documentation of laboratory confirmed leptin deficiency* associated with congenital or acquired generalized lipodystrophy **AND**
- For congenital generalized lipodystrophy only: Medical record documentation of genetic testing to confirm the diagnosis of congenital generalized lipodystrophy **AND**
- No medical record documentation of human immunodeficiency virus (HIV) or congenital or acquired partial lipodystrophy **AND**
- Medical record documentation of an insufficient response to at least 6 months on a physician supervised diet program **AND**
- Medical record documentation that Myalept will be reconstituted with bacteriostatic water for injection in members 18 years of age and older **AND**
- Medical record documentation of one or both of the following:
    - A diagnosis of diabetes (including baseline hemoglobin A1C (HbA1C) value) **AND** failure (defined by HbA1C greater than or equal to 8.5% on maximum recommended dose) on, intolerance to, or contraindication to at least one formulary antidiabetic agent from three classes, one of which must be insulin;
    - A diagnosis of hypertriglyceridemia (including baseline triglyceride level greater than or equal to 500 mg/dL) associated with the above diagnosis **AND** failure on, intolerance to, or contraindication to at least one formulary antihyperlipidemic agent from three classes, one of which must be fenofibrate **AND** patient managed by a cardiologist

*Leptin reference ranges:

Pediatric male and female

5-9.9 Years 0.6-16.8 ng/mL
10-13.9 Years 1.4-16.5 ng/mL
14-17.9 Years 0.6-24.9 ng/mL

Adult Lean Subjects (18-71 Years) with BMI range of 18-25

Male 0.3-13.4 ng/mL
Female 4.7-23.7 ng/mL

Adult Subjects (19-60 Years) with BMI range of 25-30

Male 1.8-19.9 ng/mL
Female 8.0-38.9 ng/mL

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial authorization will be for 6 months. For continuation of coverage, medical record documentation of improvement in objective measures associated with the complications related to congenital or acquired generalized lipodystrophy (i.e.: hemoglobin A1c (HbA1c), fasting blood sugar, triglycerides) is required. Subsequent approvals will be for 6 months.

If an exception is made, Myalept will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

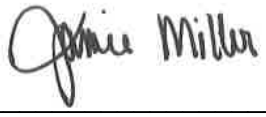
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 338.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Myalept** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature & prescribed criteria, corrected 2 typos |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 339.0**

**SECTION: Commercial Drug**
**SUBJECT: Zontivity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zontivity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zontivity may be made for members who meet **ALL** of the following criteria:

**History of Myocardial Infarction (MI)**

- Medical record documentation of a myocardial infarction (MI) occurring less than 12 months prior to starting therapy **AND**
- Medical record documentation of NO prior history of stroke, transient ischemic attack, or intracranial hemorrhage **AND**
- Medical record documentation of concomitant therapy with aspiring alone, a thienopyridine (clopidogrel) alone, or a combination of aspirin and clopidogrel

**Peripheral Arterial Disease (PAD)**

- Medical record documentation of peripheral arterial disease (PAD) as indicated by a history of intermittent claudication **AND**
- Medical record documentation of a resting ankle/brachial index (ABI) of less than 0.85 **OR** amputation, peripheral bypass, or peripheral angioplasty of the extremities secondary to ischemia **AND**
- Medical record documentation of NO prior history of stroke, transient ischemic attack, or intracranial hemorrhage **AND**
- Medical record documentation of concomitant therapy with aspirin alone, a thienopyridine (clopidogrel) alone, or a combination of aspirin and clopidogrel

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Zontivity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

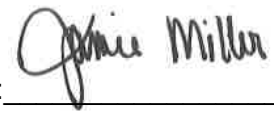
**FORMULARY ALTERNATIVES:**

cilostazol, clopidogrel, dipyridamole, pentoxifylline, ticlopidine, aspirin/dipyridamole ER, Brilinta, prasugrel*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, changed Aggrenox to aspirin/dipyridamole ER |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated Effient to generic, corrected typo |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 340.0**

**SECTION: Commercial Drug**
**SUBJECT: Grastek**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Grastek for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Grastek may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Grastek is prescribed by an allergist, immunologist or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 5 years and less than or equal to 65 years **AND**
- Medical record documentation of Timothy grass pollen or cross-reactive grass pollen induced allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots **AND**
- Medical record documentation that Grastek will not be used in combination with sublingual immunotherapy (e.g., Odactra, Oralair, and Ragwitek) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** 1 tablet per day, 30 day supply per fill should apply, 180 tablets per 365 days

**NOTE:** If the pollen season is longer than 3 months, a quantity limit exception equivalent to the time necessary for treatment through the remainder of the pollen season will be approved.

If an exception is made, Grastek will be paid for under the member's prescription drug benefit.

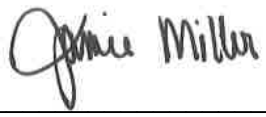
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, removed PA indicator from levocetirizine, added desloratadine to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & prescribed criteria, updated QL to match package size |
| Revised: | 5/29/18 – added (immunologist, EAI, uncontrolled asthma); updated (therapeutic failure to 3 alternatives, added additional SLIT not to be used in combo, form. alt.) |
| Revised: | 3/1/19 – annual review, updated note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 341.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Oralair**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oralair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Oralair may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Oralair is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 10 years and less than or equal to 65 years **AND**
- Medical record documentation of grass pollen induced (Timothy, Orchard, Sweet Vernal, Kentucky Blue Grass, Perennial Rye) allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots **AND**
- Medical record documentation that Oralair will not be used in combination with sublingual immunotherapy (e.g., Grastek, Odactra, and Ragwitek) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** 1 tablet per day, 30 day supply per fill should apply, 210 tablets per 365 days

**NOTE:** If the pollen season is longer than 3 months, a quantity limit exception equivalent to the time necessary for treatment through the remainder of the pollen season will be approved.

If an exception is made, Oralair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/22/14
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, removed PA indicator from levocetirizine, added desloratadine to FA
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, updated QL to match package size, removed duplicate approval language
Revised: 5/29/18 – added (immunologist, EAI, uncontrolled asthma); updated (therapeutic failure to 3 alternatives, added additional SLIT not to be used in combo, form. alt.)
Revised: 3/1/19 – annual review, updated note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 342.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ragwitek**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ragwitek for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ragwitek may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Ragwitek is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 18 years and less than or equal to 65 years **AND**
- Medical record documentation of short ragweed pollen induced allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots **AND**
- Medical record documentation that Ragwitek will not be used in combination with sublingual immunotherapy (e.g., Grastek, Odactra, and Oralair) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** 1 tablet per day, 30 day supply per fill should apply, 180 tablets per 365 days

**NOTE:** If the pollen season is longer than 3 months, a quantity limit exception equivalent to the time necessary for treatment through the remainder of the pollen season will be approved.

If an exception is made, Ragwitek will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/22/14
Revised: 10/1/14 – corrected typo
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, removed PA indicator from levocetirizine, added desloratadine to FA
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, updated QL to match package size
Revised: 5/29/18 – added (immunologist, EAI, uncontrolled asthma); updated (therapeutic failure to 3 alternatives, added additional SLIT not to be used in combo, form. alt.)
Revised: 3/1/19 – annual review, updated note

Geisinger

**POLICY NUMBER: 342.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ragwitek**

Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 343.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zydelig**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zydelig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zydelig may be made for members who meet the following criteria:

**CLL**

- Medical record documentation that Zydelig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed chronic lymphocytic leukemia (CLL) **AND**
- Medical record documentation of concurrent use with rituximab

**FL**

- Medical record documentation that Zydelig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior systemic therapies

**SLL**

- Medical record documentation that Zydelig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed small lymphocytic lymphoma (SLL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior systemic therapies

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Zydelig is configured as a prior authorization for new starts only. Zydelig will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Zydelig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

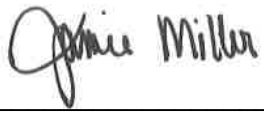
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 343.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Zydelig** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/22/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria, updated format of headers, updated QL to match package size |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 344.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Controlled Substance DUR Denial**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for controlled substance DUR denials for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of the requested controlled substance may be made for members who meet the following criteria:

- A concurrently prescribed medication precludes the use of a controlled substance

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, the requested controlled substance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

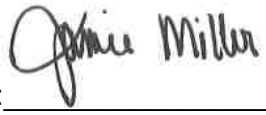
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 344.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Controlled Substance DUR Denial** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/6/14 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 6/8/15 – updated criteria, renamed policy |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 348.0**

**SECTION: Commercial Drug**
**SUBJECT: Sivextro Tablets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sivextro tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Sivextro tablets may be made for members who meet the following criteria:

- Medical record documentation that patient is greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of a grade 2 or greater acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus,* or *Enterococcus faecalis* which have been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that Sivextro therapy was started during an inpatient setting

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets

**AUTHORIZATION DURATION:** one-time, 6 day approval, RX count 1

If an exception is made, Sivextro tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

clindamycin, cefaclor, cefadroxil, cefdinir, cefditoren, cefpodoxime, cefprozil, cefuroxime, cephalexin, azithromycin, clarithromycin, Ery-tab, erythromycin base, erythromycin ethylsuccinate, erythromycin stearate, amoxicillin, amoxicillin/clav, dicloxacillin, penicillin C, ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin, demeclocycline, doxycycline, minocycline, tetracycline

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/1/14
Revised: 2/9/15 – added grade 2 infection or greater & revised inpatient criteria
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, corrected typo
Revised: 3/1/19 – annual review, added QL approval note, added RX count
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – updated age from 18 to 12 years
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Reviewed: 3/1/23 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 348.0**

**SECTION: Commercial Drug**
**SUBJECT: Sivextro Tablets**

Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 349.0**

**SECTION: Commercial Drug**
**SUBJECT: Karbinal ER**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Karbinal ER for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Karbinal ER may be made for members who meet the following criteria:

- Medical record documentation that patient is greater than or equal to 2 years of age **AND**
- Medical record documentation that Karbinal ER is being used for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to over-the-counter loratadine, over-the-counter cetirizine, over-the-counter fexofenadine, over-the-counter levocetirizine, immediate release carbinoxamine, diphenhydramine, **AND** chlorpheniramine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Karbinal ER will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

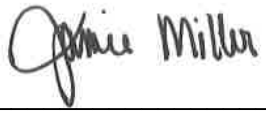
**FORMULARY ALTERNATIVES:**

carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, desloratadine, dexchlorpheniramine, diphenhydramine, promethazine

| Geisinger | POLICY NUMBER: 349.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Karbinal ER |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 12/1/14 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, defined FDA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature title; updated FA; updated levocetirizine to OTC |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 350.0**

**SECTION: Commercial Drug**
**SUBJECT: Bydureon BCise**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bydureon BCise for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Bydureon BCise may be made for members who meet the following criteria:

- For members 18 years of age and older: medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus **OR**
- For members between 10 and 18 years of age: medical record documentation of therapeutic failure on, intolerance to or contraindication to Victoza

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

If an exception is made, Bydureon BCise will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Ozempic*, Victoza*, Rybelsus*, Trulicity*

*prior authorization required

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 350.0**

**SECTION: Commercial Drug**
**SUBJECT: Bydureon BCise**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/13/15 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, added Toujeo, Jardiance, Invokana, Synjardy, & Invokamet to FA, updated PA/ST indicator |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, corrected typo in FA |
| Revised: | 1/17/18 – added step language, removed failure of Tanzeum and added Ozempic, updated FA, updated signature |
| Revised: | 3/1/18 – annual review, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note, updated QL, updated FA |
| Revised: | 1/28/20 – added failure of Rybelsus, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, corrected Rybelsus typo |
| Revised: | 1/21/22 – added criteria for members 10-18 years of age |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated policy to BCise; removed ST language; updated FA |
| Revised: | 3/1/24 – annual review; updated signature title |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 351.0**

**SECTION: Commercial Drug**
**SUBJECT: Tudorza Pressair**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tudorza Pressair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tudorza Pressair may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Spiriva **AND** Incruse Ellipta, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Spiriva **AND** Incruse Ellipta

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Tudorza Pressair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

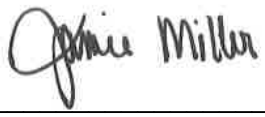
**FORMULARY ALTERNATIVES:**

Spiriva HandiHaler, Spiriva Respimat, Incruse Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 351.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Tudorza Pressair** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/13/15 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added step therapy language |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 5/24/19 – added failure of Incruse Ellipta |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 352.0**

**SECTION: Commercial Drug**
**SUBJECT: Droxidopa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for droxidopa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of droxidopa may be made for members who meet the following criteria:

- Medical record documentation that droxidopa is prescribed by a cardiologist or neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to midodrine **AND** fludrocortisone **AND**
- Medical record documentation of a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by:
    - Primary autonomic failure (Parkinson's Disease, multiple system atrophy, and pure autonomic failure) **OR**
    - Dopamine beta-hydroxylase deficiency **OR**
    - Non-diabetic autonomic neuropathy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of four (4) weeks. Subsequent approvals with be for an additional three (3) months, requiring medical record documentation of continued or sustained improvement in the symptoms of neurogenic orthostatic hypotension (NOH).

If an exception is made, droxidopa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 352.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Droxidopa |

**FORMULARY ALTERNATIVES:**
midodrine, fludrocortisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/9/15 |
| Reviewed: | 3/1/15 – annual review |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, updated prescribed criteria, corrected typo |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Northera to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

| Geisinger | POLICY NUMBER: 353.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Evzio |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Evzio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Evzio may be made for members who meet the following criteria:

- Patient or caregiver is administering medication outside of a healthcare facility, such as a personal residence or school **AND**
- Medical record documentation of a diagnosis or reason why the patients is at an increased risk of opioid-induced respiratory depression* **AND**
- Medical record documentation of a reason why the patient cannot use generic naloxone syringes **AND** naloxone (Narcan) Nasal Spray

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** (One) 1 syringe per fill

**NOTE:** According to the Evzio website, diagnoses or reasons why patients would be at an increased risk of opioid-induced respiratory depression include:

- History of, or potential for, substance abuse, dependence, and/or addiction
- Accidental exposure and/or unintentional opioid misuse
  - Includes members of the patients' household who may discover and use the prescribed opioid inappropriately
- Prescribed a morphine-equivalent dose of opioids greater than or equal to 20 mg/day
- Currently switching to a different opioid
- Chronic pulmonary disease
- Sleep apnea
- Asthma
- Chronic kidney and/or liver impairment
- Uses CNS depressants (includes benzodiazepines and alcohol)

- Uses certain medications for depression (for example, monoamine oxidase inhibitors)

If an exception is made, Evzio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

naloxone 1 mg/mL prefilled syringe, naloxone 0.4 mg/mL prefilled syringe, nasal spray (generic Narcan), Kloxxado, Opvee, Zimhi

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/9/15 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review, removed PA indicator from FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode character, defined abbreviations, updated FA |
| Revised: | 3/27/17 – rationale for not using Narcan |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 6/17/19 – removed counseling requirement (approved at 5/2015 P&T meeting) |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated Narcan to include naloxone in criteria |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 353.0**

**SECTION: Commercial Drug**
**SUBJECT: Evzio**

Revised: 3/1/24 – annual review; updated signature; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 354.0**

**SECTION: Commercial Drug**
**SUBJECT: Cerdelga**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cerdelga for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Cerdelga may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a confirmed diagnosis of Type 1 Gaucher disease along with at least one of the following conditions:
  - anemia; or
  - thrombocytopenia; or
  - bone disease; or
  - hepatomegaly or splenomegaly **AND**
- Medical record documentation that member is a CYP2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) as detected by a Food and Drug Administration (FDA) cleared test **AND**
- Medical record documentation that Cerdelga is recommended by a metabolic specialist with experience in treating Gaucher disease

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Cerdelga will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

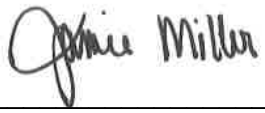
**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 354.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Cerdelga |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/9/15 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, updated age and prescriber criteria |
| Revised: | 3/1/19 – annual review, corrected typo |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 355.0**

**SECTION: Commercial Drug**
**SUBJECT: Zorvolex**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zorvolex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zorvolex may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of mild to moderate acute pain of osteoarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three formulary nonsteroidal anti-inflammatory drugs (NSAIDs), including:
  - At least one of the following: diclofenac sodium, diclofenac potassium, or diclofenac sodium/misoprostol **AND**
  - At least one of the following: nabumetone, meloxicam, or etodolac

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Zorvolex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diclofenac sodium/misoprostol, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

| Geisinger | POLICY NUMBER: 355.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Zorvolex |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/9/15 |
| Reviewed: | 3/1/15 – annual review |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated bullet formatting of FA criteria |
| Revised: | 3/1/18 – annual review, updated signature, corrected typo |
| Revised: | 3/1/19 – annual review, defined NSAIDs |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 356.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Bunavail**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bunavail for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Bunavail may be made for members who meet the following criteria:

- Must be prescribed for the treatment of opioid dependence and the prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Member must be initially referred to and actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- For re-authorization, the member must be adherent to Bunavail therapy and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
- Behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements. Continued approval for the drug is dependent on cooperation with this effort **AND**
- Medical record documentation of rationale for why the member cannot use buprenorphine/naloxone SL tablets **AND** buprenorphine/naloxone SL films

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 4.2/0.7 mg and 6.3/1 mg dosage forms: two (2) per day
  - 2.1/0.3 mg dosage form: one (1) per day

**AUTHORIZATION DURATION:** If approved, initial authorization duration will be 3 months. If approved, subsequent authorization duration will be 12 months.

If an exception is made, Bunavail will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
buprenorphine/naloxone sublingual film, buprenorphine/naloxone sublingual tablet

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/9/15
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – removed dose reduction requirement
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 10/10/17 – removed induction therapy, added auth duration
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note, removed PA indicator from FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 6/8/21 – removed in network requirement, removed counseling attestation, updated UDS requirement, removed form/attestation criteria, updated alternative criteria, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 358.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Harvoni and Ledipasvir /Sofosbuvir 90/400 mg tablet**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Harvoni and ledipasvir/sofosbuvir 90/400 mg tablet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Harvoni and ledipasvir/sofosbuvir 90/400 mg tablet may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years using weight-based dosing **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; with decompensated cirrhosis, in combination with ribavirin (if eligible) **AND**
- Medical record documentation of METAVIR liver scoring or cirrhosis assessment by a non-invasive test **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 6 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel **AND**

- Medical record documentation of receiving the following within a reasonable timeframe:
    - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin, if indicated **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
    - Hepatitis B immunization series **OR**
    - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
        - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
        - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
    - Is being treated for human immunodeficiency virus (HIV) **OR**
    - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**NOTES:**

1. Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).
2. Guidelines can be referenced at www.hcvguidelines.org.

**TREATMENT DURATION:**
Consistent with AASLD/ IDSA Guidelines (8 weeks, 12 weeks, 24 weeks)

**8 weeks duration is only for treatment-naïve, Genotype 1 patients who are HIV-uninfected and whose HCV RNA level is < 6million IU/ml

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, if request is for ledipasvir/sofosbuvir 90/400 mg tablet include generic only.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 90-400 mg and 45-200 mg tablets: 1 tablet per day, 28 day supply per fill
  - 45-200 mg pellets: 2 packets per day, 28 day supply per fill
  - 37.5-150 mg pellets: 1 packet per day, 28 day supply per fill

**APPROVAL LANGUAGE:** Meets criteria, auth x (?) weeks, RX count= (?), (28 day supply/fill), generic only [when applicable]. QL: 1 tab/day (QL for LETTER only)

If an exception is made, Harvoni or ledipasvir/sofosbuvir 90/400 mg tablet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 358.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Harvoni and Ledipasvir /Sofosbuvir 90/400 mg tablet |

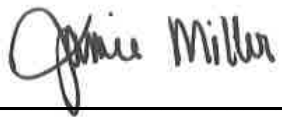
**FORMULARY ALTERNATIVES:**

Mavyret*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/9/15
Reviewed: 3/1/15 – annual review
Revised: 4/13/15 – added Genotype 3
Revised: 10/1/15 – added use of Viekira, updated FA
Revised: 1/29/16 – added HBV/HIV to definitions, added hepatocellular screening criterion, added severe extrahepatic manifestations of hep C criterion, removed in writing from member commitment, removed use of Viekira Pak
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – added G5 & G6; added/updated regimen for G1, G4 G5, & G6, added auth duration for G5 & G6, corrected typo in auth duration, removed no S/S of decompensated liver disease requirement
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – removed G3, corrected typo in treatment duration, added reauth criteria
Revised: 7/27/16 – added F2 fibrosis, updated D/A requirement, updated FA
Revised: 12/7/16 – update drug and alcohol criteria. Removed substance abuse treatment compliance, UDS corresponding with fill history, counseling by GHP. Added Sovaldi to FA.
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 6/2/17 – added regimen supported by compendia, added ribavirin for treatment experienced/compensated cirrhosis, removed incomplete course with same DAA, added non-liver co-morbid conditions to life expectancy, removed fibrosis requirement/liver manifestations, added METAVIR score
Revised: 8/8/17 – revised age criteria to age 12 OR weight greater than 35 kg
Revised: 11/27/17 – added failure of Mavyret, updated FA, updated signature

| | |
|---|---|
| Revised: | 1/19/18 – removed prescriber, added Hep B & HIV criteria, updated FA |
| Revised: | 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS, corrected typo |
| Revised: | 12/28/18 – added HCV positive transplant indication/FA criteria, added COE |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 7/23/19 – added TPA COE exclusion, renamed to generic |
| Revised: | 01/28/20 – updated age criteria to age 3 and weight based dosing, edited treatment duration to consistent with AASLD/IDSA Guidelines and removed continuation criteria |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – added QL for pellets |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed AtlantiCare & St. Lukes, added Harvoni to policy title |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 7/25/23 – removed prior treatment criterion, generic Harvoni from FA; updated diagnosis criterion, METAVIR scoring criterion, baseline labs within 6 months, HCV RNA within reasonable timeframe, notes, signature title; added approval language; updated/moved concurrent ribavirin criterion |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 362.0**

**SECTION: Commercial Drug**
**SUBJECT: Lynparza**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lynparza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lynparza may be made for members who meet the following criteria:

**For Ovarian Cancer**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

**If the member is in complete/partial response to first-line platinum based chemotherapy:**

- Medical record documentation of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer **AND**
- Medical record documentation member has had a complete or partial response to first-line platinum based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance treatment **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of deleterious or suspected deleterious germline or somatic BRCA-mutation (*gBRCA*m or *sBRCAm*) **OR**
  - Medical record documentation of both of the following:
    - Documentation of homologous recombination deficiency (HRD)-positive status with a deleterious or suspected deleterious *BRCA* mutation **AND**

- Documentation that Lynparza will be prescribed in combination with bevacizumab

**OR**

**If the member has platinum-sensitive recurrent disease and has completed two or more lines of platinum-based chemotherapy:**

- Medical record documentation of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance therapy

**For Metastatic Breast Cancer**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCA*m, HER2-negative metastatic breast cancer **AND**
- Medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting **AND**
- If hormone receptor (HR)-positive, medical record documentation that prior treatment included endocrine therapy or documentation that endocrine therapy would be considered inappropriate

**For Adjuvant Treatment of High Risk Early Breast Cancer**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious gBRCAm, HER2-negative high risk early breast cancer* **AND**
- Medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant or adjuvant setting

***NOTE:** In the OlympiA trial, high risk was defined as follows:

- Prior Neoadjuvant Chemotherapy:
  - Triple Negative Breast Cancer (TNBC) or Hormone Receptor Positive Breast cancer must have had residual invasive cancer in the breast and/or the resected lymph nodes (non-pathologic complete response) at the time of surgery.
  - Hormone Receptor Positive Breast Cancer must also have had a score of ≥3 based on pre-treatment clinical and post-treatment pathologic stage

(CPS), estrogen receptor (ER) status, and histologic grade as shown in the Table 1 below.

**Table 1. Early Breast Cancer Stage, Receptor Status, and Grade Scoring Requirements for Study Enrollment**

| Stage/feature | | Points |
|---|---|---|
| **Clinical Stage (pre-treatment)** | I/IIA | 0 |
| | IIB/IIIA | 1 |
| | IIIB/IIIC | 2 |
| **Pathologic Stage (post-treatment)** | 0/I | 0 |
| | IIA/IIB/IIIA/IIIB | 1 |
| | IIIC | 2 |
| **Receptor status** | ER positive | 0 |
| | ER negative | 1 |
| **Nuclear grade** | Nuclear grade 1-2 | 0 |
| | Nuclear grade 3 | 1 |

- Prior Adjuvant Chemotherapy:
  - TNBC must have had node positive disease or node negative disease with a ≥ 2cm primary tumor
  - Hormone Receptor Positive, HER2-negative breast cancer must have had ≥ 4 pathologically confirmed positive lymph nodes

**For Metastatic Pancreatic Adenocarcinoma**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCA*m metastatic pancreatic adenocarcinoma **AND**
- Medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy

**For Metastatic Castration-Resistant Prostate Cancer**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) **AND**
  - Medical record documentation of progression following prior treatment with Xtandi or Zytiga **AND**
  - Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**OR**

- Medical record documentation of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC)
  **AND**
- Medical record documentation that Lynparza will be used in combination with abiraterone and prednisone or prednisolone

**NOTE**: The FDA approved test is the BRACAnalysis CDx™. The FoundationOne CDx™ is also FDA approved for Lynparza for ovarian and prostate cancer.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION**:
**For first-line maintenance of BRCA-mutated advanced ovarian cancer (failure on first-line platinum-based chemotherapy) and for first-line maintenance of HRD-positive advanced ovarian cancer in combination with bevacizumab:**
Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval for Lynparza will be granted for up to an additional 12 months (total of two years of therapy) and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease

For members requesting approval of treatment beyond two (2) years, medical record documentation will be required showing patient has continued evidence of disease and treating healthcare provider believes member can derive further benefit from continuous treatment. Each additional approval will be for a period of 12 months. Members with complete response at two years, will not be granted additional treatment, per the package labeling.

**For adjuvant treatment of high-risk early breast cancer:**
One time authorization for 12 months or less if the reviewing provider feels it is medically appropriate.

Authorization of Lynparza for the adjuvant treatment of high-risk early breast cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

**For all other indications:**
Initial approval will be for 12 months or less if the reviewing provider feels it is medical appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If an exception is made, Lynparza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/13/15
Reviewed: 3/1/16 – annual review

| | |
|---|---|
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/24/17 – increased authorization duration to 12 months |
| Revised: | 11/27/17 – added tablets, updated format of age/prescriber for capsules, updated sig. |
| Revised: | 3/1/18 – annual review, added grandfather language, updated prescriber criteria |
| Revised: | 4/6/18 – added breast cancer indication to tablets |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/28/19 – removed capsules criteria, added first-line main. indication, updated auth duration |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 4/21/20 – separated indications with headers, added pancreatic cancer indication |
| Revised: | 7/29/20 – Restructured ovarian cancer criteria, added HRD ovarian cancer & prostate cancer |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 1/21/22 – removed epithelial, fallopian tube, & peritoneal CA under failure of 3 or more therapies |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 4/6/22 – updated QL to match package size for one month |
| Revised: | 6/7/22 – added adjuvant treatment of high-risk early breast cancer indication |
| Revised: | 10/6/22 – deleted indication for ovarian CA after failure of 3 or more prior lines of chemo |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 10/5/23 – updated signature title; added BRCAm mCRPC indication |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 365.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ofev**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ofev for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ofev may be made for members who meet the following criteria:

**Interstitial Pulmonary Fibrosis (IPF)**

- Medical record documentation that the diagnosis of interstitial pulmonary fibrosis (IPF) is made by an interdisciplinary team including, but not limited to, specialists from Pulmonary Medicine, Radiology, Thoracic Surgery, Pathology, and/or Rheumatology **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of idiopathic pulmonary fibrosis (IPF), confirmed by one of the following:
  - A usual interstitial pneumonia (UIP) pattern on high resolution CT (HRCT) scan alone **OR**
  - Both high resolution CT (HRCT) and surgical lung biopsy pattern suggestive of idiopathic pulmonary fibrosis (IPF) or probable IPF
- Medical record documentation of the exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity) **AND**
- Medical record documentation that the patient was taught pulmonary rehabilitation techniques **AND**
- Medical record documentation that Ofev and Esbriet are not being used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day, 30 day supply per fill

**Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)**

- Prescription written by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) **AND**
- Medical record documentation of systemic sclerosis related to interstitial lung disease confirmed by all of the following:
    - Greater than or equal to 10% fibrosis on a chest high resolution computer tomography **AND**
    - FVC greater than or equal to 40% of predicted normal **AND**
    - DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day, 30 day supply per fill

**Note:** ACR/ELAR Diagnostic Criteria for Systemic Sclerosis

| Item | Sub-item(s) | Weight/score† |
|---|---|---|
| Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints *(sufficient criterion)* | – | 9 |
| Skin thickening of the fingers *(only count the higher score)* | Puffy fingers | 2 |
| | Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints) | 4 |
| Fingertip lesions *(only count the higher score)* | Digital tip ulcers | 2 |
| | Fingertip pitting scars | 3 |
| Telangiectasia | – | 2 |
| Abnormal nailfold capillaries | – | 2 |
| Pulmonary arterial hypertension and/or interstitial lung disease *(maximum score is 2)* | Pulmonary arterial hypertension | 2 |
| | Interstitial lung disease | 2 |
| Raynaud's phenomenon | – | 3 |
| SSc-related autoantibodies (anticentromere, anti–topoisomerase I [anti–Scl-70], anti–RNA polymerase III) *(maximum score is 3)* | Anticentromere | 3 |
| | Anti–topoisomerase I | |
| | Anti–RNA polymerase III | |

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).
† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥9 are classified as having definite SSc.

**Chronic Fibrosing Interstitial Lung Disease (ILDs) with a Progressive Phenotype**

- Prescription written by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype* **AND**
- Medical record documentation of chronic interstitial lung disease confirmed by all of the following:
    - Greater than or equal to 10% fibrosis on a chest high resolution computer tomography **AND**
    - FVC greater than or equal to 45% of predicted normal **AND**
    - DLCO (diffusion capacity of the lung for carbon monoxide) 30-80% of predicted normal **AND**
- Medical record documentation of interstitial lung disease progression despite appropriate management with documentation of one of the following:
    - FVC decline greater than or equal to 10% **OR**
    - FVC decline 5% to less than 10% with documentation of either worsening symptoms **OR** increasing fibrotic changes on imaging **OR**
    - Documentation of both worsening symptoms AND increasing fibrotic changes on imaging

***NOTE:** Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype includes, but is not limited to:

- Rheumatoid arthritis associated ILD (RA-ILD)
- Mixed connective tissue disease
- Chronic hypersensitivity pneumonitis (HP)
- Idiopathic nonspecific interstitial pneumonia (iNSIP)
- Unclassifiable idiopathic interstitial pneumonia (uIIP)
- Exposure-related ILD
- Sarcoidosis

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day, 30 day supply per fill

If an exception is made, Ofev will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

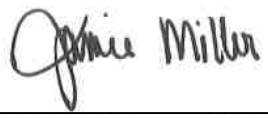
**FORMULARY ALTERNATIVES:**

Interstitial Pulmonary Fibrosis: Esbriet*
Systemic Sclerosis-Associated Interstitial Lung Disease: none
Chronic Fibrosing Interstitial Lung Diseases: none

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/13/15 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, updated QL to match package size |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 01/28/20 – added SSc-ILD indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/17/20 – added ILDs indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, removed symbols |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 366.0**

**SECTION: Commercial Drug**
**SUBJECT: Pirfenidone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pirfenidone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of pirfenidone may be made for members who meet the following criteria:

- Medical record documentation that the diagnosis of interstitial pulmonary fibrosis (IPF) is made by an interdisciplinary team including, but not limited to, specialists from Pulmonary Medicine, Radiology, Thoracic Surgery, Pathology, and/or Rheumatology **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of idiopathic pulmonary fibrosis (IPF), confirmed by one of the following:
  - A usual interstitial pneumonia (UIP) pattern on high resolution CT (HRCT) scan alone **OR**
  - Both high resolution CT (HRCT) and surgical lung biopsy pattern suggestive of IPF or probable IPF
- Medical record documentation of the exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity) **AND**
- Medical record documentation that the patient was taught pulmonary rehabilitation techniques **AND**
- Medical record documentation that pirfenidone and Ofev are not being used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 9 capsules per day, 30 day supply per fill

If an exception is made, pirfenidone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

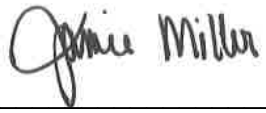
**FORMULARY ALTERNATIVES:**

Ofev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/13/15 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, updated QL to match package size |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 11/1/23 – updated signature; updated Esbriet to pirfenidone |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 367.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ibrance |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ibrance for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Ibrance may be made for members who meet the following criteria:

**Ibrance as Initial Endocrine Therapy**

- Medical record documentation that Ibrance is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hormone receptor positive (HR-positive), HER2 negative advanced or metastatic breast cancer **AND**
- Ibrance is bring prescribed as initial endocrine based therapy in postmenopausal women **OR** men receiving testicular steroidogenesis suppression treated with a luteinizing hormone-releasing hormone (LHRH) agonist (i.e., goserelin, etc.) **AND**
- Medical record documentation that Ibrance will be prescribed in combination with an aromatase inhibitor (i.e., letrozole, etc.)

**Ibrance Following Disease Progression on Endocrine Therapy**

- Medical record documentation that Ibrance is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hormone receptor positive (HR-positive), HER2 negative advanced or metastatic breast cancer **AND**
- Ibrance is being prescribed after disease progression following endocrine therapy **AND**
- Medical record documentation that Ibrance is being used in combination with fulvestrant **AND**

- **If the request is for a pre/peri-menopausal woman:** Medical record documentation that the member is receiving ovarian suppression with a luteinizing hormone-releasing hormone (LHRH) agonist (i.e., goserelin, etc.)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 21 capsules per 28 days, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Ibrance is configured as a prior authorization for new starts only. Ibrance will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Ibrance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

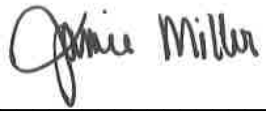
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 367.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Ibrance** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/13/15 |
| Revised: | 12/16/15 – Corrected quantity limit |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – added use in combination with fulvestrant |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 6/2/17 – removed age, added advanced BC, clarified indications, updated auth dur. |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 5/24/19 – separated indications, added men to initial endocrine, re-formatted LHRH criteria |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 368.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Velphoro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Velphoro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Velphoro may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease requiring dialysis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcium acetate **AND** sevelamer carbonate **AND** lanthanum carbonate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Velphoro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

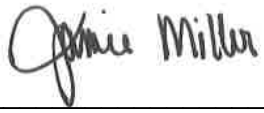
**FORMULARY ALTERNATIVES:**

calcium acetate, sevelamer carbonate, lanthanum carbonate, Fosrenol powder packet

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 368.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Velphoro |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/13/15 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Revised: | 4/5/18 – updated FA criteria to generics and removed Ca level info, updated FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 371.0**

**SECTION: Commercial Drug**
**SUBJECT: Belsomra**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Belsomra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Belsomra may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of insomnia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Belsomra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

eszopiclone, zaleplon, zolpidem, zolpidem ER, amitriptyline, mirtazapine, trazodone, estazolam, flurazepam, quazepam, temazepam, triazolam

| Geisinger | POLICY NUMBER: 371.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Belsomra |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/5/15 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, removed QL from FA |
| Revised: | 3/1/17 – annual review removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 373.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lenvima**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lenvima for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lenvima may be made for members who meet the following criteria:

**Thyroid Cancer**

- Medical record documentation that Lenvima is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer

**Renal Cell Carcinoma**

- Medical record documentation that Lenvima is prescribed by an oncologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of use in combination with everolimus (generic Afinitor) for surgically unresectable advanced or metastatic renal cell carcinoma with predominant clear-cell histology **AND**
    - Medical record documentation of a therapeutic failure on or intolerance to one prior anti-angiogenic therapy, including, but not limited to, sunitinib (generic Sutent), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), everolimus (generic Afinitor), or Torisel (temsirolimus)

    **OR**

    - Medical record documentation in combination with pembrolizumab for the treatment of advanced renal cell carcinoma (RCC) **AND**

- Medical record documentation the Lenvima in combination with pembrolizumab (Keytruda) are being used as first-line treatment for advanced disease

**Hepatocellular Carcinoma**

- Medical record documentation that Lenvima is prescribed by a hematologist or oncologist **AND**
- Medical record documentation that Lenvima is being used for the treatment of unresectable hepatocellular carcinoma (HCC) **AND**
- Medical record documentation that patient has Child-Pugh Class A liver disease **AND**
- Medical record documentation that patient has not received prior therapy for unresectable hepatocellular carcinoma **AND**
- Medical record documentation that the appropriate dose of Lenvima is prescribed based on patient's body weight (greater than 60kg: Lenvima 12mg once daily, less than 60kg: Lenvima 8mg once daily)

**Endometrial Cancer**

- Medical record documentation that Lenvima is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
- Medical record documentation of disease progression following at least one prior systemic therapy **AND**
- Medical record documentation that the member is not a candidate for curative surgery or radiation **AND**
- Medical record documentation that tumors are **not** microsatellite instability-hihg (MSI-H) or mismatch repair deficient (dMMR) **AND**
- Medical record documentation that Lenvima will be given in combination with pembrolizumab (Keytruda)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 4 mg daily dose pack: 1 capsule per day, 30 days supply per fill
  - 8 mg daily dose pack: 2 capsules per day, 30 days supply per fill
  - 10 mg daily dose pack: 1 capsule per day, 30 days supply per fill
  - 12 mg daily dose pack: 3 capsules per day, 30 days supply per fill
  - 14 mg daily dose pack: 2 capsules per day, 30 days supply per fill

- 18 mg daily dose pack: 3 capsules per day, 30 days supply per fill
- 20 mg daily dose pack: 2 capsules per day, 30 days supply per fill
- 24 mg daily dose pack: 3 capsules per day, 30 days supply per fill

**RE-AUTHORIZATION CRITERIA:** Lenvima is configured as a prior authorization for new starts only. Lenvima will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Lenvima will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Renal Cell Carcinoma: Caprelsa*, Cometriq*, sorafenib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/15
Reviewed: 3/1/16 – annual review

Geisinger

**POLICY NUMBER: 373.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lenvima**

Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/22/16 – added RCC indication
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, updated format of headers
Revised: 12/28/18 – added HCC indication, updated FA
Revised: 3/1/19 – annual review, added QL approval note, updated QL from 1/19 P&T
Revised: 10/28/19 – corrected hepatocellular carcinoma typo
Revised: 11/20/19 – added endometrial carcinoma indication
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/1/21 – added use with pembrolizumab for RCC, added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed symbols
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature; updated FA: corrected typo

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 375.0**

**SECTION: Commercial Drug**
**SUBJECT: Savaysa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Savaysa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Savaysa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of stroke and systemic embolism risk reduction in patients with non-valvular atrial fibrillation **OR**
- Medical record documentation that Savaysa is being used for treatment of deep vein thrombosis and/or pulmonary embolism **AND** one of the following:
  - Patient weight greater than 60 kg **OR**
  - Patient weight less than or equal to 60 kg **AND** Savaysa being dosed as 30 mg per day
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Eliquis **AND** Xarelto

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Savaysa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

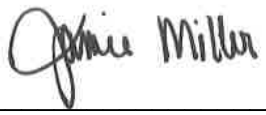
**FORMULARY ALTERNATIVES:**

warfarin, Eliquis, Xarelto

| Geisinger | POLICY NUMBER: 375.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Savaysa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/5/15 |
| Revised: | 9/21/15 – corrected typos |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 376.0**

**SECTION: Commercial Drug**
**SUBJECT: Mircera**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mircera for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Mircera may be made for members who meet the following criteria:

For new starts:

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis **AND**
- Medical record documentation of hemoglobin (hgb) less than 10 g/dL for new starts **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For continuation of therapy, a repeat hemoglobin (hgb) no greater than 3 months old should be submitted. The following criteria will apply to requests for continuation of therapy:

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis **AND**
- Medical record documentation of hemoglobin (hgb) less than 12 g/dL for continuation of therapy **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

**NOTE:** In individuals whose hemoglobin (hgb) is greater than or equal to 12 g/dL or rises by 1 g/dL in any two-week period, additional doses should be withheld or reduced.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

| Geisinger | POLICY NUMBER: 376.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Mircera |

**AUTHORIZATION DURATION:** 3 months

If an exception is made, Mircera will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

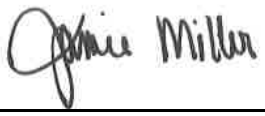
**FORMULARY ALTERNATIVES:**

Epogen*, Procrit*, Aranesp*, Retacrit*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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| Devised: | 6/5/15 |
| Revised: | 9/21/15 – corrected typos |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/7/22 – added chelation to ferritin/transferrin criterion; updated continuation req.; updated note |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 379.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Cosentyx**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cosentyx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For Plaque Psoriasis**

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation that Cosentyx is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine or phototherapy **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- 75 mg every 4 weeks
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 2 with a duration of one-month.
        - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 0.5 mL per 28 days
- 150 mg every 4 weeks
    1. In NCRx: Add Treat as "Include" Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
    2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
        - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days
- 300 mg every 4 weeks
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
        - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 2 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

cyclosporine, methotrexate

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop);

triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**For Psoriatic Arthritis**
An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documentation history of psoriasis **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- **For peripheral disease:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **OR**
- **For axial disease:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **AND**
- If the request is for a pediatric member, medical record documentation that the prescribed dosing is appropriate for member's weight

**NOTE:**
For pediatric patients weighing ≥ 15 kg and < 50 kg: Inject 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

For pediatric patients weighing ≥ 50 kg: Inject 150mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- 75 mg every 4 weeks
    1. In NCRx: Add Treat as "Include" Process Modifier, Ignore Misc Handler, number of claims authorization 1, max quantity dispensed 2 with a duration of one month.
        - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 0.5 mL per 28 days

- 150 mg every 4 weeks
    1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
    2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
        - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days
- 300 mg every 4 weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
        - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 2 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For Ankylosing Spondylitis**
An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the medication is being dose as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- 150 mg every 4 weeks
    1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
    2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
        - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days
- 300 mg every 4 weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
        - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 2 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For Non-radiographic Axial Spondylarthritis (nr-axSpA):**
An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of at least one of the following:
    - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
    - Sacroiliitis on magnetic resonance imaging (MRI)

**AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- 150 mg every 4 weeks
    1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
    2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
        - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days

**RE-AUTHORIZATION CRITERIA:** Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For Enthesitis-Related Arthritis**
An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of enthesitis-related arthritis **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight

**NOTE:**
For pediatric patients weighing ≥ 15 kg and < 50 kg: Inject 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

For pediatric patients weighing ≥ 50 kg: Inject 150mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- 75 mg every 4 weeks
    1. In NCRx: Add Treat as "Include" Process Modifier, Ignore Misc Handler, number of claims authorization 1, max quantity dispensed 2 with a duration of one month.
        - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 0.5 mL per 28 days
- 150 mg every 4 weeks
    1. In NCRx: Add Treat as "Include" Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
    2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
        - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days

**RE-AUTHORIZATION CRITERIA:** Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

none

**For Hidradenitis Suppurativa**
An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe hidradenitis suppurativa (HS), defined as Stage II or III on the Hurley staging system* **AND**
- Medical record documentation that Cosentyx is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of at least 3 abscesses or inflammatory nodules **AND**
- Medical record documentation of concomitant use of oral or systemic antibiotics **AND**
- Medical record documentation that the member has received counseling on weight management (if overweight) and smoking cessation (if the member is an active smoker) **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- If requesting a dose of 300 mg every 2 weeks, medical record documentation that the member has been compliant with every 4 week administration of Cosentyx **AND**
- If requesting a dose of 300 mg every 2 weeks, medical record documentation of therapeutic failure on every 4 week administration of Cosentyx

***NOTE:** Hurley Staging System

- Stage I: A single lesion without sinus tract formation.
- Stage II: More than one lesion or area, but with limited tunneling.
- Stage III: Multiple lesions, with more extensive sinus tracts and scarring.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- 300 mg every 4 weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
        - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 2 mL per 28 days
- 300 mg every 2 weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, max script quantity 4.
        - QL FOR LETTER: 4 mL per 28 days

**RE-AUTHORIZATION CRITERIA:** Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

adalimumab-FKJP*, Hadlima*, Yusimry*, Humira*

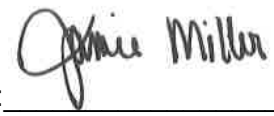
*prior authorization required

If an exception is made, Cosentyx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 7/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/22/16 – added psoriatic arthritis and ankylosing spondylitis indications
Revised: 3/1/17 – annual review, removed Unicode characters, corrected typo in RA auth durat.
Revised: 3/24/17 – annual review, corrected RA criteria to PsO

| | |
|---|---|
| Revised: | 8/8/17 – updated induction QL's for all indications |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria |
| Revised: | 5/30/18 – added combination with other biologic agents, updated therapeutic failures, updated FA |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 6/4/19 – updated QL and added authorization parameters |
| Revised: | 10/12/20 – added non-radiographic axial spondylarthritis |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/22/21 – updated approval level from NDC to GPI-10, updated/corrected QL language, removed auth duration, added reauth criteria, updated age to 6 for PsO, added QL for 75 mg for PsO |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered |
| Revised: | 6/7/22 – added Enthesitis-related arthritis ind., updated age, note, & QL for PsA |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives in PsO section |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated auth entry parameters |
| Revised: | 4/10/24 – added HS indication |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 380.0**

**SECTION: Commercial Drug**
**SUBJECT: Rytary**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rytary for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Rytary may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Parkinson's disease, post-encephalitis parkinsonism, **OR** parkinsonism which may follow carbon monoxide intoxication or manganese intoxication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be immediate release carbidopa/levodopa

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Rytary will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

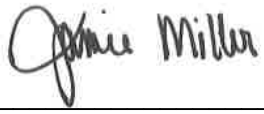
**FORMULARY ALTERNATIVES:**

carbidopa/levodopa ODT, carbidopa/levodopa tablet, carbidopa/levodopa ER tablet, carbidopa/levodopa/entacapone, pramipexole, ropinirole, ropinirole ER, bromocriptine, selegiline, amantadine, benztropine, trihexyphenidyl, rasagiline

| Geisinger | POLICY NUMBER: 380.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Rytary |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/15 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 381.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Namzaric**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Namzaric for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Namzaric may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe Alzheimer's dementia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on memantine **AND** donepezil used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Namzaric will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

memantine, donepezil, galantamine, rivastigmine

Geisinger

**POLICY NUMBER: 381.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Namzaric**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/15 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 382.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Corlanor**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Corlanor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Corlanor may be made for members who meet the following criteria:

- Medical record documentation that Corlanor is prescribed by a cardiologist **AND**
- Medical record documentation of being in sinus rhythm with resting heart rate greater than or equal to the lower limit of the normal range based on age* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the maximum tolerated dose of 2 formulary beta-blockers, one of which must be carvedilol **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of age greater than or equal to 18 years **AND**
        - Medical record documentation of stable, symptomatic heart failure with a left ventricular ejection fraction less than or equal to 35% **AND**
        - Medical record documentation of hospitalization for worsening heart failure within the previous 12 months

    **OR**
    - Medical record documentation of age greater than or equal to 6 months and less than 18 years **AND**
        - Medical record documentation of stable, symptomatic heart failure due to dilated cardiomyopathy **AND**
        - Medical record documentation of class II to IV heart failure according to New York Heart Association [NYHA] functional class or Ross classification **AND**
        - Medical record documentation of a left ventricular ejection fraction less than or equal to 45%

**AND**

- If the request is for Corlanor Solution: Documentation of one of the following:
    - Medical record documentation of member weight less than 40 kg **OR**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Corlanor tablets **OR**
- Medical record documentation that member has dysphagia or is unable to swallow tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tablets: 2 tablets per day
  - Solution: 20 mL per day

***NOTE: Lower limit of normal heart rate based on age**

- Age 6 - 12 months: HR ≥ 105 bpm
- Age 1 - 3 years: HR ≥ 95 bpm
- Age 3 - 5 years: HR ≥ 75 bpm
- Age 5 and older: HR ≥ 70 bpm

If an exception is made, Corlanor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

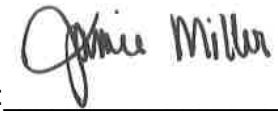
**FORMULARY ALTERNATIVES:**

carvedilol, metoprolol succinate, bisoprolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 382.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Corlanor** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/15 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 10/12/20 – updated HR criteria to be based on age, added criteria for 6 months-18 years, added criteria for solution, added QL for solution, added HR table |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 383.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Natpara**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Natpara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Natpara may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hypocalcemia secondary to hypoparathyroidism **AND**
- Medical record documentation that Natpara is prescribed by an endocrinologist **AND**
- Medical record documentation of no increased baseline risk for osteosarcoma **AND**
- Medical record documentation that previous treatment with calcium supplements and active forms of vitamin D were not successful in treated hypocalcemia **AND**
- Medical record documentation that Natpara will be used concurrently with a calcium supplement

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 cartridges (1 pack) per 28 days

**AUTHORIZATION DURATION**: Authorization duration will be for a period of 6 months. Reauthorization will require the following criterion be met:

- Medical record documentation that the lowest dose of Natpara is being used to achieve a total serum calcium (albumin-corrected) within the lower half of the normal total serum calcium range (approximately 8.0 to 9.0 mg/dL)

If an exception is made, Natpara will be paid for under the member’s prescription drug benefit.

| Geisinger | **POLICY NUMBER: 383.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Natpara** |

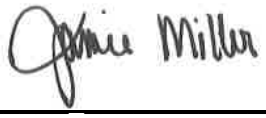
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/15 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, corrected typo |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 384.0**

**SECTION: Commercial Drug**
**SUBJECT: Lisdexamfetamine**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lisdexamfetamine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of lisdexamfetamine may be made for members who meet the following criteria:

**ADHD**

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CDΩ **AND** amphetamine/dextroamphetamine SR combination

Ω = **From the Metadate CD package insert, "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g., water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed."**

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule or chewable tablet per day

**Binge Eating Disorder**

- Medical record documentation of binge eating disorder made by a licensed mental health provider with the number of binge eating episodes per week documented **AND**
- Medical record documentation that member is a non-responder to psychotherapy **OR** member is receiving concurrent psychotherapy

**AUTHORIZATION DURATION**: Authorization will be for a period of six (6) months. Reauthorization will require documentation showing a lower number of binge eating episodes per week compared to baseline.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule or chewable tablet per day

If an exception is made, lisdexamfetamine will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**ADHD**

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD

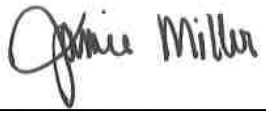
**Binge Eating Disorder**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 384.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lisdexamfetamine** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/15 – devised new policy utilizing ADHD criteria from policy 94.0. See policy 94.0 for previous policy updates. Binge eating disorder added. |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated format of headers & ADHD criteria, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/20/19 – added QL |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 10/25/23 – updated signature title; updated to generic only |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 385.0**

**SECTION: Commercial Drug**
**SUBJECT: Zubsolv**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zubsolv for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Zubsolv may be made for members who meet the following criteria:

- Must be prescribed for the treatment of opioid dependence and the prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Member must be initially referred to and actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- For re-authorization member must be adherent to Zubsolv therapy and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
- Behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements. Continued approval for the drug is dependent on cooperation with this effort **AND**
- Medical record documentation of rationale for why the member cannot use buprenorphine/naloxone SL tablets **AND** buprenorphine/naloxone SL films

**AUTHORIZATION DURATION:** If approved, initial authorization duration will be 3 months. If approved, subsequent authorization duration will be 12 months.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 34 day supply per fill

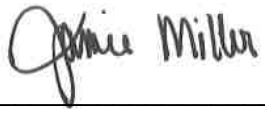
If a formulary exception is approved Zubsolv will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
buprenorphine/naloxone sublingual tablets, buprenorphine/naloxone sublingual films

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/15 |
| Reviewed: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure, updated approval statement to Zubsolv |
| Revised: | 5/27/16 – removed dose reduction requirement |
| Revised: | 7/27/16 – extended renewal authorization to 12 months |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature, removed QL indicator |
| Revised: | 3/1/19 – annual review, removed PA indicator from FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 6/8/21 – removed in network, criteria, removed, buprenorphine/naloxone criteria, updated re-auth bullet, updated FA bullet, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 386.0**

**SECTION: Commercial Drug**
**SUBJECT: Cresemba Capsules**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cresemba capsules for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Cresemba capsules may be made for members who meet the following criteria:

**Treatment of Aspergillosis and Mucormycosis**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis **OR** for the treatment of invasive mucormycosis

**Prophylaxis of Aspergillosis and Candida**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole

**AUTHORIZATION DURATION:** 3 months. Reauthorization will be based on the following criteria:

- Medical record documentation of a culture and sensitivity showing the isolates are susceptible to Cresemba **AND**
- Medical record documentation that the appropriate dose is being prescribed (2 capsules per day)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day

If a formulary exception is approved Cresemba capsules will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

itraconazole*, voriconazole suspension, voriconazole tablets*#

*prior authorization required, #quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/19/15 |
| Revised: | 12/7/15 – updated QL to read 2 capsules per day only |
| Revised: | 3/1/16 – annual review, corrected typo in first bullet |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria, removed QL indicator |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 8/24/21 – added prophylaxis of aspergillosis and Candida indication |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 386.0**

**SECTION: Commercial Drug**
**SUBJECT: Cresemba Capsules**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 387.0**

**SECTION: Commercial Drug**
**SUBJECT: Cholbam**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cholbam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Cholbam may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
  - Bile acid synthesis disorders due to single enzyme defects (SEDs) **OR**
  - Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption **AND**
- Medical record documentation that diagnosis has been confirmed with an abnormal urinary bile acid by Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis **AND**
- Medical record documentation that Cholbam is prescribed by a gastroenterologist, hepatologist, or metabolic specialist with experience in the diagnosis and treatment of bile acid synthesis and peroxisomal disorders **AND**
- For the treatment of peroxisomal disorders: medical record documentation that Cholbam will be used as adjunctive therapy **AND**
- Medical record documentation of baseline alanine aminotransferase/aspartate aminotransferase (ALT/AST), total bilirubin, and body weight

**AUTHORIZATION DURATION:** Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of a response to therapy, defined as the following:

- Member must meet at least two of the following laboratory criteria **OR** one laboratory criterion and the clinical weight criterion
  - Laboratory Criteria:

- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) values reduced to less than 50 U/L, or baseline levels reduced by 80%
- Total bilirubin values reduced to less than or equal to 1 mg/dL; and
- No evidence of cholestasis on liver biopsy

- Clinical Criteria
  - Body weight increased by 10% or stable at greater than the 50th percentile; and

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

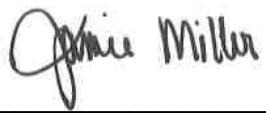
If a formulary exception is approved Cholbam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/19/15
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review

Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 388.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Rexulti**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rexulti for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Rexulti may be made for members who meet the following criteria:

**Schizophrenia**

- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three generic, formulary atypical antipsychotics

**Major Depressive Disorder**

- Medical record documentation of a diagnosis of major depressive disorder (MDD) **AND** medical record documentation that the patient is using Rexulti as adjunctive therapy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of combination therapy with aripiprazole and an antidepressant **AND**
- One of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of combination antidepressant therapy (such as a selective serotonin reuptake inhibitor [SSRI] and bupropion

or a serotonin and norepinephrine reuptake inhibitor [SNRI] and bupropion) OR
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of an antidepressant with augmentation therapy (including, but not limited to lithium, valproate, carbamazepine and lamotrigine)

**Agitation Associated with Dementia due to Alzheimer's Disease**

- Medical record documentation of a diagnosis of agitation associated with dementia due to Alzheimer's Disease **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three generic, formulary antipsychotics used for the treatment of agitation associated with dementia (such as but not limited to quetiapine, risperidone, olanzapine, etc.) **AND**
- Medical record documentation that Rexulti will not be used "as needed" for this indication

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved Rexulti will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Schizophrenia**: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone, Seroquel XR

**MDD**:

- Selective serotonin reuptake inhibitor (SSRI): citalopram, fluoxetine, paroxetine, sertraline, escitalopram
- Serotonin and norepinephrine reuptake inhibitor (SNRI): duloxetine, venlafaxine, desvenlafaxine
- Bupropion

- Tricyclic Antidepressants: amitriptyline, desipramine, doxepin, imipramine, nortriptyline
- Mirtazapine
- Augmentation Therapy: lithium, valproate, carbamazepine and lamotrigine

**Agitation Associated with Dementia due to Alzheimer's Disease**: aripiprazole, clozapine, olanzapine, quetiapine, risperidone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/19/15 |
| Revised: | 3/1/16 – annual review, added OR to MDD criteria |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 7/14/16 – updated bullet formatting for MDD alternatives |
| Revised: | 3/1/17 – annual review, defined abbrev., removed Unicode characters, updated FA |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria, corrected typo |
| Revised: | 3/1/19 – annual review, added QL approval note, removed note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 4/6/22 – split criteria by indication, updated age for schizophrenia to 13 years |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 11/1/23 – updated signature title; added agitation assoc. w/ dementia due to Alzheimer's disease |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 390.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Afrezza**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Afrezza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Afrezza may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that the patient does not have asthma or chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation that the patient is unable to use subcutaneous insulin due to a clinically justifiable reason (i.e., patient is unable to hold/maneuver syringes/pens*) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Novolog

***NOTE**: Fear of needles is not considered a clinically justifiable reason for not using subcutaneous insulin.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved Afrezza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

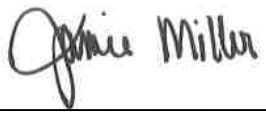
**FORMULARY ALTERNATIVES:**

Novolog, insulin aspart

| Geisinger | POLICY NUMBER: 390.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Afrezza |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/19/15 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 392.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Praluent**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Praluent for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***Therapeutic failure to statins, Zetia, fibrates, and/or bile acid sequestrants*** – inability to reach target LDL goals (<100 mg/dL for primary prevention in HeFH or HoFH or <70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
7. ***Intolerance to statins*** – increased LFT's, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persists after two retrials with a different dose or different dosing strategy (i.e., every other day administration) of alternatives moderate- or high-intensity statin
8. ***Contraindication to statins*** – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

**PROCEDURE:**

A formulary exception for coverage of Praluent may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Primary hyperlipidemia **OR**
  - Heterozygous familial hypercholesterolemia **AND** either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **OR**
  - Homozygous familial hypercholesterolemia (HoFH) **AND** either:

  - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
  - Diagnosis made based on a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL AND either xanthoma before 10 years of age OR evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
  - Low-density lipoprotein (LDL) greater than 100 if the member is using Praluent for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 70 if the member is using Praluent for secondary prevention **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of one of the following:
  - Member is currently on and adherent to (taking at least 90% of the prescribed doses over the past three months) ezetimibe in combination with a maximally tolerated dose of a statin and LDL-C remains above goal **OR**
  - Intolerance or contraindication to ezetimibe **OR**
  - Member is currently on and adherent to (taking at least 90% of prescribed doses over the past three months) a maximally tolerated dose of a statin **OR** the patient is statin- intolerant **AND** an LDL-C is more than 20% above goal **AND**
- Medical record documentation that Praluent is not being used in combination with another PCSK9 inhibitor

Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 mL per 28 days

**AUTHORIZATION DURATION:** Initial authorizations for Praluent will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Praluent continues to not be used in combination with another PCSK9 inhibitor

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

| | Criteria | Score |
|---|---|---|
| **Family history** | First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile | 1 |
| | First-degree relative with Tx and/or children <18 with LDL-C >95th centile | 2 |
| **Clinical history** | Patient has premature CAD* | 2 |
| | Patient has premature cerebral/peripheral vascular disease | 1 |
| **Physical examination** | Tx | 6 |
| | Arcus cornealis below the age of 45 years | 4 |
| **LDL-C** | >8.5 mmol/L (more than ~330 mg/dL) | 8 |
| | 6.5-8.4 mmol/L (~250-329 mg/dL) | 5 |
| | 5.0-6.4 mmol/L (~190-249 mg/dL) | 3 |
| | 4.0-4.9 mmol/L (~155-189 mg/dL) | 1 |
| **Definite FH** | | Score >8 |
| **Probable FH** | | Score 6-8 |
| **Possible FH** | | Score 3-5 |
| **No diagnosis** | | Score <3 |

If a formulary exception is approved Praluent will be paid for under the member's prescription drug benefit.

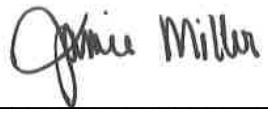
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin, rosuvastatin, ezetimibe, colesevelam, cholestyramine, colestipol, fenofibrate, fenofibric acid, gemfibrozil

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/22/15
Revised: 11/18/15 – added bile acid sequestrants (BAS) to therapeutic failure definition, removed rhabdomyolysis from intolerance definition, added lipidologist to prescriber criteria, added within 3 months to baseline LDL criteria, updated failure on statin wording, added max LDL criteria to BAS criteria, clarified concomitant therapy criteria and PCSK9 adherence reauth criteria, added statin adherence to reauth criteria, added "*Prior auth required" wording in formulary alternatives
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – Updated failure of statin definition, updated intolerance to statins definition, added ASCVD to diagnosis, added PCSK9 and Apo B to HeFH diagnosis, added LDL values to baseline LDL requirement, updated Crestor to rosuvastatin, removed LDL > 70 from statin requirement, updated combination therapy bullet, added fibrate to bile acid sequestrant requirements, added no combination use with PCSK9, Juxtapid, or Kynamro to initial and renewal criteria, updated FA
Revised: 3/1/17 – annual review, removed Unicode, defined abbrev., updated Zetia to ezetimibe

| | |
|---|---|
| Revised: | 6/2/17 – revised statin bullet, removed combo therapy bullet, added if statin toleration to reauth |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber & age criteria, corrected typo |
| Revised: | 12/28/18 – removed failure of BAS |
| Revised: | 3/1/19 – annual review, added QL approval note, removed GPID approval |
| Revised: | 10/1/19 – extended initial auth duration to 12 months |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, reinserted LOB table |
| Revised: | 6/4/21 – added diag. of primary hyperlipidemia & HoFH, updated baseline LDL requirement, removed references to Kynamro |
| Revised: | 11/24/21 – removed specialist requirement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 4/6/22 – updated ESC/EAS to Dutch Lipid and HoFH mutations, removed combo with Juxtapid |
| Revised: | 1/1/23 – updated ezetimibe criteria |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 393.0**

**SECTION: Commercial Drug**
**SUBJECT: Repatha**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Repatha for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***Therapeutic failure to statins, ezetimibe, fibrates, and/or bile acid sequestrants*** – inability to reach target LDL goals (<100 mg/dL for primary prevention in HeFH or HoFH or <70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
7. ***Intolerance to statins*** – increased LFT's, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persists after two retrials with a different dose or different dosing strategy (i.e., every other day administration) of alternatives moderate- or high-intensity statin
8. ***Contraindication to statins*** – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

**PROCEDURE:**

A formulary exception for coverage of Repatha may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Primary hyperlipidemia **OR**
  - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **OR**
  - Homozygous familial hypercholesterolemia (HoFH) **AND** either:

  - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (APOB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
  - Diagnosis made based on a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy
  - Low-density lipoprotein (LDL) greater than 130 mg/dL if the member is greater than or equal to 10 years of age and less than 18 years of age **OR**
  - Low-density lipoprotein (LDL) greater than 100 mg/dL if the member is greater than or equal to 18 years of age and using Repatha for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 70 mg/dL if the member is using Repatha for secondary prevention **AND**
- Medical record documentation of age greater than or equal to 18 years if the diagnosis is clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia **OR** medical record documentation of age greater than or equal to 10 years if the diagnosis is homozygous familial hypercholesterolemia (HoFH) **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of one of the following:
  - Member is currently on and adherent to (taking at least 90% of the prescribed doses over the past three months) ezetimibe in combination with a maximally tolerated dose of a statin and LDL-C remains above goal **OR**
  - Intolerance or contraindication to ezetimibe **OR**
  - Member is currently on and adherent to (taking at least 90% of prescribed doses over the past three months) a maximally tolerated dose of a statin **OR** the patient is statin- intolerant **AND** an LDL-C is more than 20% above goal **AND**
- Medical record documentation that Repatha is not being used in combination with another PCSK9 inhibitor **AND**
- If requesting Repatha Syringe or Repatha Sureclick 420 mg dose (3 mL), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex **OR**

- If requesting 420 mg every 2 weeks:
  - Medical record documentation of a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
  - One of the following:
    - Medical record documentation that the member has been on 420 mg once monthly for 12 weeks and a clinically meaningful response has not been achieved **OR**
    - Medical record documentation that the member is on lipid apheresis every 2 weeks

Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Pen/Syringe: 2 mL per 28 days
  - Pushtronex: 3.5 mL per 28 days

**AUTHORIZATION DURATION:** Initial authorizations for Repatha will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Repatha continues to not be used in combination with another PCSK9 inhibitor **AND**
- If requesting Repatha Syringe or Repatha Sureclick 420 mg dose (3 mL), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex **OR**

- If requesting 420 mg every 2 weeks:
  - Medical record documentation of a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
  - One of the following:
    - Medical record documentation that the member has been on 420 mg once monthly for 12 weeks and a clinically meaningful response has not been achieved **OR**
    - Medical record documentation that the member is on lipid apheresis every 2 weeks

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

| | Criteria | Score |
|---|---|---|
| **Family history** | First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile | 1 |
| | First-degree relative with Tx and/or children <18 with LDL-C >95th centile | 2 |
| **Clinical history** | Patient has premature CAD* | 2 |
| | Patient has premature cerebral/peripheral vascular disease | 1 |
| **Physical examination** | Tx | 6 |
| | Arcus cornealis below the age of 45 years | 4 |
| **LDL-C** | >8.5 mmol/L (more than ~330 mg/dL) | 8 |
| | 6.5-8.4 mmol/L (~250-329 mg/dL) | 5 |
| | 5.0-6.4 mmol/L (~190-249 mg/dL) | 3 |
| | 4.0-4.9 mmol/L (~155-189 mg/dL) | 1 |
| **Definite FH** | | Score >8 |
| **Probable FH** | | Score 6-8 |
| **Possible FH** | | Score 3-5 |
| **No diagnosis** | | Score <3 |

If a formulary exception is approved Repatha will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin, rosuvastatin, ezetimibe, colesevelam, cholestyramine, colestipol, fenofibrate, fenofibric acid, gemfibrozil

Geisinger

**POLICY NUMBER: 393.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Repatha**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/18/15 |
| Revised: | 3/1/16 – annual review, updated Praluent reference in first line of procedure to Repatha |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 5/27/16 – Updated failure of statin definition, updated intolerance to statins definition, added PCSK9 and Apo B to HeFH diagnosis, added LDL values to baseline LDL requirement, updated Crestor to rosuvastatin, removed LDL > 70 from statin requirement, updated combination therapy bullet, added fibrate to bile acid sequestrant requirement, added no combination use with PCSK9, Juxtapid, or Kynamro to initial and renewal criteria, updated FA |
| Revised: | 7/8/16 – corrected typo in quantity limit |
| Revised: | 3/1/17 – annual review, updated Zetia to ezetimibe, removed Unicode, defined abbrev. |
| Revised: | 6/2/17 – updated statin bullet, removed combo therapy bullet, added if statin tolerant to reauth, added Pushtronex QL |
| Revised: | 8/8/17 – updated QL, added requirement to use Pushtronex for 420 mg dose |
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria, corrected typo |
| Revised: | 5/30/18 – removed failure of bile acid sequestrants |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 10/1/19 – increased initial auth duration to 12 months for all indications |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Zetia to generic in definitions |
| Revised: | 6/4/21 – added primary hyperlipidemia diag., updated baseline LDL requirements, removed references to Kynamro, added criteria to initial & renewal for 420 mg q2 week dosing |
| Revised: | 7/1/21 – added primary hyperlipidemia to age greater than 18 criteria |
| Revised: | 11/24/21 – removed specialist requirement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 4/6/22 – updated ESC/EAS to Dutch Lipid and HoFH mutations, updated ages for baseline LDL, decreased age for HoFH, removed combo with Juxtapid |
| Revised: | 1/1/23 – updated ezetimibe criteria |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 394.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Glatopa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Glatopa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Glatopa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of relapsing forms of multiple sclerosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glatiramer acetate 20 mg/mL

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 6240003010E520 & 6240003010E540)

If a formulary exception is approved Glatopa will be paid for under the member's prescription drug benefit

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

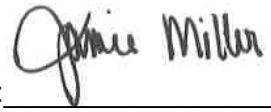
**FORMULARY ALTERNATIVES:**

glatiramer acetate, fingolimod 0.5 mg, Gilenya 0.25 mg, dimethyl fumarate, Betaseron, Plegridy, Extavia, teriflunomide 14 mg, Avonex, Rebif, Mayzent

| Geisinger | POLICY NUMBER: 394.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Glatopa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/20/15 |
| Revised: | 3/1/16 – annual review, added Gilenya, Tecfidera, and Betaseron to FA |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, updated FA |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Revised: | 3/1/19 – annual review, updated Copaxone to glatiramer |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 395.0**

**SECTION: Commercial Drug**
**SUBJECT: Orkambi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orkambi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Orkambi may be made for members who meet the following criteria:

- Medical record documentation that Orkambi is prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of patient age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of cystic fibrosis (CF) **AND**
- Medical record documentation that the member is homozygous for the *F508del* CFTR (cystic fibrosis transmembrane conductance regulator) mutation as documentation by a Food and Drug Administration (FDA)-cleared cystic fibrosis (CF) mutation test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 4 tablets per day, 30 day supply per fill
  - 2 packets per day, 28 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

If a formulary exception is approved Orkambi will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 395.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Orkambi |

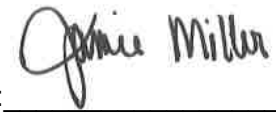
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/20/15 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 1/25/17 – updated age to 6 years |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 1/17/18 – updated prescriber criteria, auth duration to 4 months, updated signature |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 7/27/18 – removed baseline $FEV_1$ requirement, updated re-auth to improvement or stabilization of CF |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 01/28/20 – updated age to 2 years, added QL for packets |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/19/23 – updated age to 1 year |
| Revised: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 396.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lonsurf**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lonsurf for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Lonsurf may be made for members who meet the following criteria:

**Metastatic Colorectal Cancer**

- Medical record documentation that Lonsurf is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF (vascular endothelial growth factor) biological therapy, and if RAS wild-type, an anti-EGFR (epidermal growth factor receptor) therapy **AND**
- Medical record documentation that Lonsurf will be prescribed as a single agent or in combination with bevacizumab

**Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma**

- Medical record documentation that Lonsurf is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma **AND**

- Medical record documentation of previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 15 mg/6.14 mg tablet: 100 tablets per 28 days
  - 20 mg/8.19 mg tablet: 80 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Lonsurf is configured as a prior authorization for new starts only. Lonsurf will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Lonsurf will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

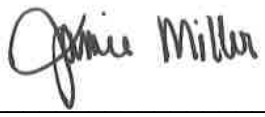
capecitabine, Stivarga*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 396.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lonsurf** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/20/15 |
| Revised: | 3/1/16 – annual review, corrected 2 typos in 4th bullet |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations, removed Unicode characters |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria, added grandfather language |
| Revised: | 6/1/18 – updated QL |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 5/24/19 – added metastatic gastric or gastroesophageal junction adenocarcinoma indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/29/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 11/1/23 – updated signature title; added use with bevacizumab to colorectal CA indication |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 397.0**

**SECTION: Commercial Drug**
**SUBJECT: Odomzo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Odomzo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Odomzo may be made for members who meet the following criteria:

- Medical record documentation that Odomzo is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy **AND**
- Medical record documentation of Odomzo treatment supported by multidisciplinary board consultation per National Comprehensive Cancer Network (NCCN) guidelines

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Odomzo is configured as a prior authorization for new starts only. Odomzo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Odomzo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

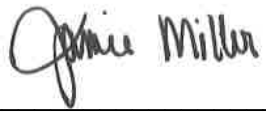
**FORMULARY ALTERNATIVES:**

Erivedge*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/20/15
Revised: 3/1/16 – annual review, corrected typo in 4th bullet
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/8/16 – updated QL to capsule
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 10/10/17 – increased authorization duration to 12 months

| | |
|---|---|
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria, added grandfather language, added DS limit |
| Reviewed: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 401.0**

**SECTION: Commercial Drug**
**SUBJECT: Cotellic**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cotellic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cotellic may be made for members who meet the following criteria:

**Metastatic Melanoma**

- Medical record documentation that Cotellic is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600E or V600K mutation as detected by aa Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of concomitant use with Zelboraf (vemurafenib)

**Histiocytic Neoplasm**

- Medical record documentation that Cotellic is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of histiocytic neoplasm (Langerhans Cell Histiocytosis, Rosai-Dorfman Disease, Erdheim-Chester Disease, Xanthogranuloma, Mixed Histiocytosis)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Cotellic is configured as a prior authorization for new starts only. Cotellic will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Cotellic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

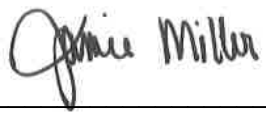
**FORMULARY ALTERNATIVES:**

Metastatic Melanoma: Mekinist*, Tafinlar*, Zelboraf*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/29/16

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 401.0**

**SECTION: Commercial Drug**
**SUBJECT: Cotellic**

Revised: 3/1/16 – annual review, corrected 2 typos in 5th bullet
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, corrected typo
Revised: 10/1/18 – added dermatologist, added "diagnosis," removed first line or no prior therapy
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 1/19/23 – added histiocytic neoplasm indication
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature; corrected typo

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 401.0**

**SECTION: Commercial Drug**
**SUBJECT: Cotellic**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cotellic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
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**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cotellic may be made for members who meet the following criteria:

**Metastatic Melanoma**

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- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600E or V600K mutation as detected by aa Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of concomitant use with Zelboraf (vemurafenib)

**Histiocytic Neoplasm**

- Medical record documentation that Cotellic is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of histiocytic neoplasm (Langerhans Cell Histiocytosis, Rosai-Dorfman Disease, Erdheim-Chester Disease, Xanthogranuloma, Mixed Histiocytosis)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Cotellic is configured as a prior authorization for new starts only. Cotellic will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Cotellic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

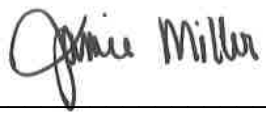
**FORMULARY ALTERNATIVES:**

Metastatic Melanoma: Mekinist*, Tafinlar*, Zelboraf*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/29/16

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 401.0**

**SECTION: Commercial Drug**
**SUBJECT: Cotellic**

Revised: 3/1/16 – annual review, corrected 2 typos in 5th bullet
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, corrected typo
Revised: 10/1/18 – added dermatologist, added "diagnosis," removed first line or no prior therapy
Revised: 3/1/19 – annual review, added QL approval note
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Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 1/19/23 – added histiocytic neoplasm indication
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature; corrected typo

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 402.0**

**SECTION: Commercial Drug**
**SUBJECT: Keveyis**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Keveyis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Keveyis may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient's condition was diagnosed by a neurologist with neuromuscular expertise **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to acetazolamide **AND**
- **For hypokalemic periodic paralysis only**: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to spironolactone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 34 day supply per fill

If a formulary exception is approved Keveyis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

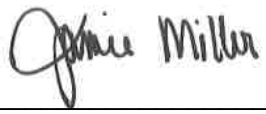
| Geisinger | POLICY NUMBER: 402.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Keveyis** |

**FORMULARY ALTERNATIVES:**

**For hyperkalemic periodic paralysis**: acetazolamide
**For hypokalemic periodic paralysis**: acetazolamide, spironolactone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/29/16 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 403.0**

**SECTION: Commercial Drug**
**SUBJECT: Ninlaro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ninlaro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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**ADDITIONAL DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Ninlaro may be made for members who meet the following criteria:

- Medical record documentation that Ninlaro is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma **AND**
- Medical record documentation that Ninlaro will be used in combination with Revlimid* and dexamethasone **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 capsules per 28 days

**RE-AUTHORIZATION CRITERIA:** Ninlaro is configured as a prior authorization for new starts only. Ninlaro will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Ninlaro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

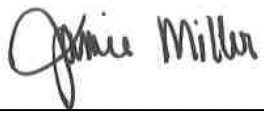
**FORMULARY ALTERNATIVES:**

Thalomid, Farydak*, Pomalyst*, Revlimid*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/29/16
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria

Revised: 3/1/19 – annual review, added QL approval note, removed GPID note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 405.0**

**SECTION: Commercial Drug**
**SUBJECT: Tagrisso**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tagrisso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Tagrisso may be made for members who meet the following criteria:

**Metastatic Non-Small Cell Lung Cancer (NSCLC)**

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of an epidermal growth factor receptor (EGFR) exon 19 deletion, EGFR exon 21L858R mutation, or EGFR T790 mutation **AND**
- Medical record documentation of one of the following:
  - If member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation: Medical record documentation that Tagrisso is being used as first-line treatment **OR**
  - If member has epidermal growth factor receptor (EGFR) T790 mutation positive disease: Medical record documentation of failure on or intolerance to prior tyrosine kinase inhibitor therapy with Iressa (gefitinib), Gilotrif (afatinib), or Tarceva (erlotinib)

**METASTATIC NSCLC AUTHORIZATION DURATION**: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease

improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**Adjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)**

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation that Tagrisso is being used as adjuvant treatment following complete tumor resection **AND**
- Medical record documentation that tumors have an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation

**ADJUVANT TREATMENT OF NSCLC AUTHORIZATION DURATION:** Initial approval will be for **12 months**. **Up to two (2)** subsequent approvals will each be for an additional 12 months or less if the reviewing provider feels it is medically appropriate to equal **a total treatment duration of 3 years** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Authorization of Tagrisso for adjuvant treatment of Non-Small Cell Lung Cancer (NSCLC) will not exceed the FDA-approved treatment duration of 3 years (36 months). For requests exceeding the above limit, documentation will be required of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

If a formulary exception is approved Tagrisso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 405.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tagrisso |

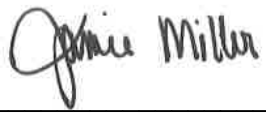
**FORMULARY ALTERNATIVES:**

EGFR T790 mutation: Gilotrif*, gefitinib*, erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/29/16 |
| Revised: | 3/1/16 – annual review |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, corrected typo |
| Revised: | 8/7/18 – added exon 19 deletion and exon 21 L858R mutations, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note, defined abbr. |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/26/21 – added adjuvant treatment of NSCLC indication |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY NUMBER: 408.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alecensa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alecensa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Alecensa may be made for members who meet the following criteria:

- Medical record documentation that Alecensa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Alecensa is configured as a prior authorization for new starts only. Alecensa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Alecensa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

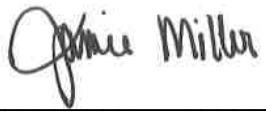
**FORMULARY ALTERNATIVES:**

Xalkori*, Zykadia*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/23/16 |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/18 – removed prior failure, updated signature, updated prescriber criteria |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 411.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Viberzi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Viberzi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Viberzi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Viberzi is prescribed by a gastroenterologist **AND**
- Medical record documentation of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation of inadequate response or intolerance to two of the following:
  - loperamide
  - antispasmodics (dicyclomine, hyoscyamine)
  - alosetron (if female) **AND**
- Medical record documentation member does not have:
  - History of severe constipation or sequelae from constipation **OR**
  - Biliary duct obstruction or sphincter of Oddi dysfunction **OR**
  - History of pancreatitis or structural disease of the pancreas **OR**
  - Excessive alcohol intake (more than 3 alcoholic beverages per day) **OR**
  - Severe hepatic impairment

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

If a formulary exception is approved Viberzi will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 411.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Viberzi |

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

alosetron (if female), dicyclomine, diphenoxylate-atropine, loperamide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/23/16 |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria, corrected typo |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 412.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Strensiq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Strensiq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Strensiq may be made for members who meet the following criteria:

- Medical record documentation that Strensiq is prescribed by an endocrinologist or metabolic specialist **AND**
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) **AND**
- Medical record documentation of low total serum alkaline phosphatase activity (see chart below for typical lowest normal reference values) **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen

**Table 2. Typical Lowest Normal Reference Values for Serum Alkaline Phosphatase Activity in North America**

| Age | Lowest Normal Total Serum or Plasma Alkaline Phosphatase Activity (U/L) | |
|---|---|---|
| | Male | Female |
| 0-30 days | 60 | 60 |
| 1-11 months | 70 | 70 |
| 1-3 years | 125 | 125 |
| 4-11 years | 150 | 150 |
| 12-13 years | 160 | 110 |
| 14-15 years | 130 | 55 |
| 16-19 years | 60 | 40 |
| >20 years | 40 | 40 |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 30 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will be for a period of 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

**NOTE:**

- Perinatal/Infantile-Onset HPP
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.
  - The dose may be increased to 3 mg/kg three times per week for insufficient efficacy.
- Juvenile-Onset HPP
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

If a formulary exception is approved Strensiq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

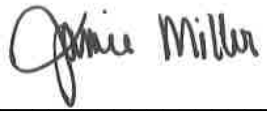
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 412.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Strensiq** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/23/16 |
| Revised: | 5/1/16 – updated format, logo, & procedure |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger Health Plan

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 413.0**

**SECTION: Commercial Drug**
**SUBJECT: Buprenorphine Buccal Film**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for buprenorphine buccal films for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).

4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
   C. In accordance with current standards of medical practice;
   D. Not primarily for the convenience of the Member, or the Member's Provider; and
   E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of buprenorphine buccal film may be made for members who meet the following criteria:

- Medical record documentation that buprenorphine buccal films are prescribed by a pain management specialist **AND**
- Medical record documentation of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 formulary alternatives, one of which must be morphine sulfate ER

**QUANTITY LIMIT:** 2 films per day

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved buprenorphine buccal film will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger Health Plan

**POLICY NUMBER: 413.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Buprenorphine Buccal Film**

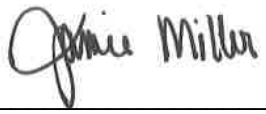
**FORMULARY ALTERNATIVES:**

fentanyl patch*, morphine sulfate extended release*, tramadol extended release*, Oxycontin*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Retired: | 8/21/18 |
| Revised: | 9/1/21 – policy reinstated, updated to generic, added GPI, clarified abbreviations |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA to include PA * |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

| Geisinger | POLICY NUMBER: 414.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Veltassa** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Veltassa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Veltassa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of mild to moderate hyperkalemia (serum potassium greater than or equal to 5.1 mEq/L and less than 6.5 mEq/L) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that attempt has been made to identify and correct the underlying cause of the patient's hyperkalemia **OR** rationale as to why the underlying cause cannot be corrected **AND**
- For mild hyperkalemia (serum potassium greater than or equal to 5.1 mEq/L and less than 5.5 mEq/L): Medical record documentation that a low potassium diet has been tried and was unsuccessful at controlling the patient's serum potassium level **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to loop diuretic or thiazide diuretic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 packet per day

If a formulary exception is approved Veltassa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 414.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Veltassa |

**FORMULARY ALTERNATIVES:**
sodium polystyrene sulfonate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |
| Revised: | 4/10/24 – updated age to 12 years |

Geisinger

**POLICY NUMBER: 415.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Meloxicam Capsules (generic Vivlodex)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for meloxicam capsules (generic Vivlodex) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of meloxicam capsules (generic Vivlodex) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of osteoarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary nonsteroidal anti-inflammatory drugs (NSAIDs), one of which must be meloxicam

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

If a formulary exception is approved meloxicam capsules (generic Vivlodex) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate,

meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Revised: | 3/1/17 – annual review, removed Unicode characters, defined abbreviations |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, added QL approval note, removed GPID note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Vivlodex to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

| Geisinger | POLICY NUMBER: 416.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Vraylar** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vraylar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Vraylar may be made for members who meet the following criteria:

**Schizophrenia or Manic/Mixed Episode associated with Bipolar I Disorder**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vraylar is being used for:
  - Schizophrenia **OR**
  - Acute treatment of manic or mixed episodes associated with bipolar I disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic, formulary atypical antipsychotics

**Bipolar Depression**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vraylar is being used for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

**Major Depressive Disorder**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder (MDD) **AND**
- Medical record documentation that the patient is using Vraylar as adjunctive therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of combination therapy with aripiprazole and an antidepressant **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of combination antidepressant therapy (such as a selective serotonin reuptake inhibitor [SSRI] and bupropion or a serotonin and norepinephrine reuptake inhibitor [SNRI] and bupropion) **OR**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of an antidepressant with augmentation therapy (including, but not limited to lithium, valproate, carbamazepine, and lamotrigine)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

If a formulary exception is approved Vraylar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Schizophrenia or Manic/Mixed Episode associated with Bipolar I Disorder: aripiprazole, clozapine, olanzapine, paliperidone*, quetiapine, risperidone, ziprasidone

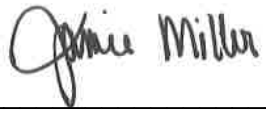
Bipolar Depression: quetiapine, olanzapine/fluoxetine

Major Depressive Disorder:
Selective serotonin reuptake inhibitor (SSRI): citalopram, fluoxetine, paroxetine, sertraline, escitalopram
Serotonin and norepinephrine reuptake inhibitor (SNRI): duloxetine, venlafaxine, desvenlafaxine
Bupropion
Tricyclic Antidepressants: amitriptyline, desipramine, doxepin, imipramine, nortriptyline
Mirtazapine
Augmentation Therapy: lithium, valproate, carbamazepine and lamotrigine

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note, removed GPID note |
| Revised: | 7/23/19 – added bipolar depression indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; added MDD indication & FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 417.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Venclexta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Venclexta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Venclexta may be made for members who meet the following criteria:

**CLL or SLL**

- Medical record documentation that Venclexta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

**AML**

- Medical record documentation that Venclexta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age 75 years or older **OR** medical record documentation of a comorbidity that precludes member from receiving intensive induction chemotherapy **AND**
- Medical record documentation of newly-diagnosed acute myeloid leukemia (AML) **AND**
- Medical record documentation that Venclexta will be used in combination with azacytidine, decitabine, or low-dose cytarabine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 10 mg tablet: 2 tablets per day, 30 day supply per fill
  - 50 mg tablet: 1 tablet per day, 30 day supply per fill
  - 100 mg tablet, 6 tablets per day, 30 day supply per fill
  - Starter Pack: 42 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Venclexta is configured as a prior authorization for new starts only. Venclexta will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Venclexta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

CLL/SLL: Imbruvica*, Calquence*, Zydelig*

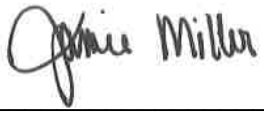
AML: Daurismo*, Tibsovo*, Idhifa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 417.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Venclexta** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria |
| Revised: | 8/21/18 – added SLL, added without 17p deletion, updated FA |
| Revised: | 2/6/19 – added AML indication, add SLL abbreviation, updated 100mg QL, added QL CSR note |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/21/19 – updated age/comorbidity criteria, updated FA |
| Revised: | 7/23/19 – removed 17p deletion requirement/note, removed prior therapy failure from CLL/SLL |
| Revised: | 2/04/20 – updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 418.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Uptravi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Uptravi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Uptravi may be made for members who meet the following criteria:

- Medical record documentation that Uptravi is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of World Health Organization (WHO) Group I, functional class II or III pulmonary hypertension **AND**
- Medical record documentation of use in combination with, or failure on, intolerance to, or contraindication to sildenafil and/or an endothelin receptor antagonist (Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Uptravi 200 mcg tablets: 140 tablets per 28 days
  - Uptravi 200-800 mcg tablet starter pack: 200 tablets per 28 days, one (1) fill per 180 days
  - All other strengths: 2 tablets per day, 30 day supply per fill

If a formulary exception is approved Uptravi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 418.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Uptravi |

**FORMULARY ALTERNATIVES:**

bosentan*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Revised: | 7/27/16 – added QL, updated FA |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 5/24/19 – updated 200 & starter pack QL, updated FA where generics available |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 419.0**

**SECTION: Commercial Drug**
**SUBJECT: Zepatier**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zepatier for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***HBV*** – Hepatitis B Virus
7. ***HCV*** – Hepatitis C Virus
8. ***HIV*** – Human Immunodeficiency Virus

**PROCEDURE:**

A formulary exception for coverage of Zepatier may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years of age **OR** weighing at least 30 kilograms **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1 or 4 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation that the member does not have moderate or severe hepatic impairment (Child-Pugh B or C) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 6 months:
    - Hepatic function panel

  - Complete blood count including differential
  - Basic metabolic panel **AND**
- Medical record documentation of receiving the following within a reasonable timeframe:
  - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
  - Hepatitis B immunization series **OR**
  - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
    - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
    - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
  - Is being treated for human immunodeficiency virus (HIV) **OR**
  - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**

- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**NOTES:**

1. Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).
2. Guidelines can be referenced at www.hcvguidelines.org.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 28 day supply per fill

**AUTHORIZATION DURATION**: Per AASLD/IDSA guidelines

**APPROVAL LANGUAGE:** Meets criteria, auth x (?) weeks, RX count= (?), (28 day supply/fill), generic only [when applicable]. QL: 1 tab/day (QL for LETTER only)

If a formulary exception is approved Zepatier will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES (if applicable):**

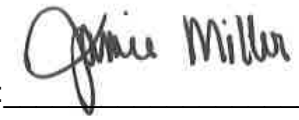
Mavyret*

*prior authorization required

| Geisinger | POLICY NUMBER: 419.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Zepatier |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/27/16 |
| Revised: | 11/22/16 – added F2 fibrosis, referral to substance use treatment. Removed 6 months abstinence, substance use treatment compliance, UDS/fill history, GHP representative. Updated FA |
| Revised: | 3/1/17 – annual review, defined abbreviations |
| Revised: | 6/2/17 – added regimen supported by compendia, added virologic relapse/failure to G4, removed failure with same DAA, added non-liver related co-morbid conditions to life expectancy, removed fibrosis/liver manifestations requirement, added METAVIR score |
| Revised: | 11/27/17 – added failure of Mavyret, updated FA, updated signature |
| Revised: | 1/19/18 – updated age format & FA, removed prescriber, added Hep B & HIV criteria |
| Revised: | 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS |
| Revised: | 12/28/18 – added HCV positive transplant indication/FA criteria, added COE |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 7/23/19 – added TPA COE exclusion |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed AtlantiCare and St Lukes |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 4/6/12 – updated age to 12 or weight ≥ 30 kg, updated auth duration to reference guidelines |
| Revised: | 3/1/23 – annual review; defined abbreviations |
| Revised: | 7/25/23 – removed prior treatment criterion; updated baseline labs within 6 months, HCV RNA within reasonable timeframe, notes, signature, authorization duration; added approval language; moved/updated ribavirin criterion |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 420.0**

**SECTION: Commercial Drug**
**SUBJECT: Cabometyx**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cabometyx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cabometyx may be made for members who meet the following criteria:

**Renal Cell Carcinoma**

- Medical record documentation that Cabometyx is prescribed by an oncologist **AND**
- Medical record documentation of use in combination with nivolumab (Opdivo) for previously untreated advanced renal cell carcinoma **OR**
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
- If the requested dose is 80 mg daily: Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not limited to, rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

**Hepatocellular Carcinoma**

- Medical record documentation that Cabometyx is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hepatocellular carcinoma (HCC) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sorafenib (Nexavar) **AND**
- If the requested dose is 80 mg daily: Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not

limited to, rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

**Differentiated Thyroid Cancer (DTC)**

- Medical record documentation that Cabometyx is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of locally advanced or metastatic differentiated thyroid cancer (DTC) **AND**
- Medical record documentation of progression following prior VEGFR-targeted therapy **AND**
- Medical record documentation that radioactive iodine-refractory or ineligible

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - If approved for 20 mg, 40 mg, or 60 mg daily dose: QL 1 per day, 30 day supply per fill
  - If approved for 80 mg daily, dosed as one 20 mg + one 60 mg tablet: QL 1 per day, 30 day supply per fill
  - If approved for 80 mg daily, dosed as two 40 mg tablets daily: QL 2 per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Cabometyx is configured as a prior authorization for new starts only. Cabometyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Cabometyx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 420.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Cabometyx |

**FORMULARY ALTERNATIVES:**

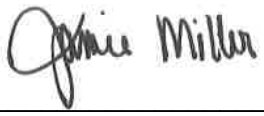
Renal Cell Carcinoma: everolimus (generic Afinitor)*, Inlyta*, Lenvima*, sorafenib*, sunitinib*, pazopanib*

Hepatocellular Carcinoma: sorafenib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/21/16 |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 10/10/17 – increased authorization duration to 12 months |
| Revised: | 1/17/18 – removed 'predominant clear-cell histology' from indication, removed prior failure, updated signature |
| Revised: | 3/1/18 – annual review, added grandfather language, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approved note, removed GPID note |
| Revised: | 3/28/19 – added HCC indication, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/26/21 – added in combination with Opdivo for advanced RCC |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 1/5/22 – added DTC indication |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY NUMBER: 421.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nuplazid**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuplazid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Nuplazid may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of Parkinson's disease psychosis (defined by illusions, a false sense of presence, hallucinations, or delusions) **AND**
- Medical record documentation that the diagnosis is established by or in consultation with a neurologist **AND**
- Medical record documentation that the psychosis is not due to other conditions (which may include, but are not limited to, another mental disorder or physiological effects of a substance)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 per day, 30 day supply per fill

**AUTHORIZATION DURATION**: Approval will be given for an initial duration of three (3) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Parkinson's disease psychosis on three (3) months of Nuplazid therapy is required.

After the initial three (3) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Parkinson's disease psychosis while on Nuplazid therapy.

If a formulary exception is approved Nuplazid will be paid for under the member's prescription drug benefit.

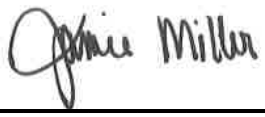
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/21/16
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age criteria, added grandfather language
Revised: 10/8/18 – updated QL
Revised: 3/1/19 – annual review, added QL approval note

Geisinger

**POLICY NUMBER: 421.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nuplazid**

| | |
|---|---|
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, removed 17 mg QL due to D/C, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 422.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Briviact**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Briviact for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Briviact may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 1 month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three formulary alternatives, one of which must be levetiracetam **AND**
- Medical record documentation that Briviact is not being used in combination with levetiracetam

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day or 20 mL per day of oral solution

If a formulary exception is approved Briviact will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 422.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Briviact |

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Patients > 1 month of age: carbamazepine, levetiracetam solution, phenobarbital, phenytoin, pregabalin

Patients > 6 months of age: levetiracetam IR

Patients > 2 years of age: lamotrigine IR, oxcarbazepine, topiramate IR, topiramate ER*

Patients > 3 years of age: gabapentin

Patients > 4 years of age: Aptiom*, lacosamide*

Additional formulary alternatives for patients over certain ages: divalproex (10+), levetiracetam ER (12+), tiagabine (12+), Fycompa* (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/22/16
Reviewed: 3/1/17 – annual review
Revised: 11/27/17 – removed adjunctive therapy requirement, updated signature
Revised: 3/1/18 – annual review, added grandfather language

Revised: 8/7/18 – updated age to 4 years, updated FA
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/15/19 – updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/22/21 – updated age to 1 month, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated FA
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 425.0**

**SECTION: Commercial Drug**
**SUBJECT: Amphetamine Tablets (generic Evekeo) & Evekeo ODT**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for amphetamine tablets (generic Evekeo) and Evekeo ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of amphetamine tablets (generic Evekeo) or Evekeo ODT may be made for members who meet the following criteria:

**Attention Deficit Hyperactivity Disorder (ADHD) (amphetamine tablets (generic Evekeo) & Evekeo ODT)**

- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of age greater than or equal to 3 years **AND**
- **For members greater than or equal to 6 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three of the following formulary alternatives: dexmethylphenidate immediate release, dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, or methylphenidate immediate release
- **For members greater than or equal to 3 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine immediate release **AND** dextroamphetamine/amphetamine immediate release

**Narcolepsy (amphetamine tablets (generic Evekeo) Only)**

- Prescription written for Evekeo **AND**
- Medical record documentation of a diagnosis of narcolepsy **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release **AND** methylphenidate immediate release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for amphetamine tablets (generic Evekeo) add generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Evekeo ODT 2.5 mg tablet: 2 tablets per day
  - Evekeo ODT 5 mg tablet: 2 tablets per day
  - Evekeo ODT 10 mg tablet: 2 tablets per day
  - Evekeo ODT 15 mg tablet: 2 tablets per day
  - Evekeo ODT 20 mg tablet: 2 tablets per day
  - Amphetamine tablets (generic Evekeo) 5 mg tablet: 3 tablets per day
  - Amphetamine tablets (generic Evekeo) 10 mg tablet: 6 tablets per day

If a formulary exception is approved amphetamine tablets (generic Evekeo) or Evekeo ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ADHD:

- **For members greater than or equal to 6 years of age:** dexmethylphenidate immediate release, dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release, atomoxetine, guanfacine extended release
- **For members greater than or equal to 3 years of age:** dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release

Narcolepsy:

dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release

| Geisinger | POLICY NUMBER: 425.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Amphetamine Tablets<br>(generic Evekeo) & Evekeo ODT |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/16 |
| Revised: | 3/1/17 – annual review, removed Unicode characters |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria & FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 11/1/21 – added Evekeo vs. Evekeo ODT distinction to each indication, added Evekeo required criterion to narcolepsy, added QL's, updated GPI level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated Evekeo tablets to generic only |

Geisinger

**POLICY NUMBER: 426.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xuriden**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xuriden for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Xuriden may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hereditary orotic aciduria as evidenced by at least one of the following:
  - Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the patient's erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone **OR**
  - Orotic acid crystals visualized in the urine via microscopy

  **AND**
- Medical record documentation of an appropriate dose for the patient's weight* **AND**
- Medical record documentation that Xuriden is prescribed by a metabolic specialist, medical geneticist, or other physician with experience in the diagnosis and treatment of inborn errors of metabolism

**NOTE:** *Appropriate dosing for Xuriden is 60 mg/kg or 120 mg/kg once daily. Xuriden is available only in 2 gram, single-use packets. The maximum daily dose should not exceed 8 grams.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 packets per day

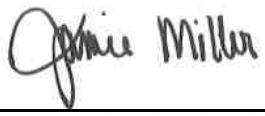
If a formulary exception is approved Xuriden will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/16 |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 428.0**

**SECTION: Commercial Drug**
**SUBJECT: Bosentan Tablets and Tracleer Tablets for Oral Suspension**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for bosentan tablets and Tracleer tablets for oral suspension for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of bosentan tablets and Tracleer tablets for oral suspension may be made for members who meet the following criteria:

- Medical record documentation that bosentan is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class II, III, or IV pulmonary arterial hypertension

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for bosentan tablets include generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

If a formulary exception is approved bosentan tablets or Tracleer tablets for oral suspension will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 428.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Bosentan Tablets and Tracleer Tablets for Oral Suspension |

**FORMULARY ALTERNATIVES:**

Uptravi*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/22/16 |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/21/19 – updated Tracleer to generic bosentan, updated all others w/ available generics |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated policy to include Tracleer tablets for oral suspension, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 429.0**

**SECTION: Commercial Drug**
**SUBJECT: Impavido**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Impavido for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Impavido may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that the patient weighs at least 30 kg **AND**
- Medical record documentation that Impavido is prescribed by a board-certified infectious disease specialist **AND**
- Medical record documentation of one of the following, confirmed by testing:
    - Visceral leishmaniasis caused by *L. donovani*
    - Cutaneous leishmaniasis caused by *L. braziliensis* **OR** *L. guyanensis* **OR** *L. panamensis*
    - Mucosal leishmaniasis caused by *L. braziliensis* **AND**
- Medical record documentation of a negative pregnancy test for women of childbearing age **AND**
- Medical record documentation member has been counseled on use of contraception during therapy and for 5 months after **AND**
- Medical record documentation of no history of Sjögren-Larsson-Syndrome **AND**
- If diagnosis is visceral leishmaniasis, medical record documentation of therapeutic failure on, intolerance to or contraindication to Liposomal Amphotericin B

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QL must be entered within authorization.*

- One-time fill for the following based on weight:
    - **30-44 kg**: 56 capsules per 28 days
    - **45 kg or greater**: 84 capsules per 28 days

**AUTHORIZATION DURATION:** one (1) month

If a formulary exception is approved Impavido will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ketoconazole, fluconazole, itraconazole*, Nebupent

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/21/16 |
| Revised: | 11/22/16 – corrected typo, updated formulary alternatives, updated formatting |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated age & prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 431.0**

**SECTION: Commercial Drug**
**SUBJECT: Taltz**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Taltz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of plaque psoriasis**
A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of four (4) preferred formulary biologics for the treatment of psoriasis **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of plaque psoriasis on Taltz therapy is required.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12; then 80 mg every 4 weeks
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, enter 3 in max number of claims authorized with a duration of 3 months
        - QL FOR LETTER: Loading dose: 8 mL per 3 months; Maintenance dose: 1 mL per 28 days

**FORMULARY ALTERNATIVES:**

Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Otezla*, Skyrizi*, Tremfya*, Cosentyx*, Cimzia*, Siliq*

*prior authorization required

**For treatment of pediatric plaque psoriasis**
A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that the prescribed dosage is appropriate for the member's weight **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on at least two (2) topical corticosteroids **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of pediatric plaque psoriasis on Taltz therapy is required.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg every 4 weeks
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, max quantity dispensed 2, max number of claims authorized 1, with a duration of 1 month
        - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days

**FORMULARY ALTERNATIVES:**

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**For treatment of psoriatic arthritis**
A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a dermatologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of psoriatic arthritis **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriatic arthritis on Taltz therapy is required.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**NOTE:** If member has coexistent plaque psoriasis, the loading dose quantity limit should be entered as outlined under the plaque psoriasis subsection of the Taltz criteria.

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg every 4 weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, max quantity dispensed 2, max number of claims authorized 1, with a duration of 1 month
        - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Cosentyx*, Enbrel*, Otezla*, Skyrizi*, Tremfya*, Rinvoq*, Xeljanz/XR*, Cimzia*, Orencia*, Simponi*

*prior authorization required

**For treatment of ankylosing spondylitis**
A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of ankylosing spondylitis **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of ankylosing spondylitis on Taltz therapy is required.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg every 4 weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, max quantity dispensed 2, max number of claims authorized 1, with a duration of 1 month
        - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days

**FORMULARY ALTERNATIVES:**
Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Cosentyx*, Rinvoq*, Xeljanz/XR*

*prior authorization required

**For treatment of non-radiographic axial spondyloarthropathy**
A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of at least one of the following:
    - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
    - Sacroiliitis on magnetic resonance imaging (MRI)

**AND**

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of non-radiographic axial spondylarthritis **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of non-radiographic axial spondyloarthropathy on Taltz therapy is required.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 mL per 28 days

**FORMULARY ALTERNATIVES:**
Cosentyx*, Cimzia*, Rinvoq*

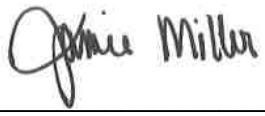
*prior authorization required

If a formulary exception is approved Taltz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/21/16 |
| Revised: | 11/22/16 – updated formatting, changed > to greater than |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria |
| Revised: | 4/10/18 – added indication headers, PP (removed failure of Enbrel, added failure of Cosentyx, added no other agent), added PsA indication, updated FA |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 11/22/19 – updated FA |
| Revised: | 1/28/20 – added ankylosing spondylitis indication, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 4/20/20 – added note under PsA indication, defined QL |
| Revised: | 10/12/20 – added pediatric plaque psoriasis & non-radiographic axial spondylarthritis, corrected typo in auth duration to address appropriate indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered |
| Revised: | 4/6/22 – updated loading dose for PsA, AS, and ped. PsO from 3 mL to 2 mL |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives in pediatric PsO section |
| Revised: | 1/1/23 – updated to allow Taltz after failure of 4 preferred agents & FA for PsO, updated to allow Taltz after failure of 3 preferred agents & FA for PsA, AS, & nr-axSpA; added auth duration for all indications |

Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature; updated FA; updated auth entry parameters

Geisinger

**POLICY NUMBER: 432.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zembrace Symtouch**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zembrace Symtouch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions
- Policy 296.0 Triptan Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Zembrace Symtouch may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of migraines with or without aura **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 different preferred alternative triptan products (one of which must be a generic sumatriptan injection)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 mL per 28 days

If a formulary exception is approved Zembrace Symtouch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

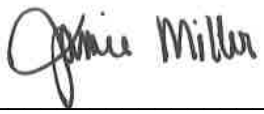
| Geisinger | POLICY NUMBER: 432.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Zembrace Symtouch** |

**FORMULARY ALTERNATIVES:**
naratriptan^, rizatriptan^, sumatriptan^, zolmitriptan^

^quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/21/16 |
| Revised: | 11/22/16 – updated formatting and formulary alternatives |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature & age criteria, added AND after 3rd criteria, defined QL |
| Revised: | 3/1/19 – annual review, updated QL |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 434.0**

**SECTION: Commercial Drug**
**SUBJECT: Epclusa and Sofosbuvir/Velpatasvir**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epclusa and sofosbuvir/velpatasvir for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***HBV*** – Hepatitis B Virus
7. ***HCV*** – Hepatitis C Virus
8. ***HIV*** – Human Immunodeficiency Virus

**PROCEDURE:**

A formulary exception for coverage of Epclusa and sofosbuvir/velpatasvir may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years **AND**
- Medical record documentation that proper weight-based dosing is being prescribed **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis or in combination with ribavirin in patients with decompensated cirrhosis (if eligible) **AND**
- Medical record documentation of METAVIR liver scoring or cirrhosis assessment by a non-invasive test **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**

- Medical record documentation of receiving the following within the past 6 months:
  - Hepatic function panel
  - Complete blood count including differential
  - Basic metabolic panel **AND**
- Medical record documentation of receiving the following within a reasonable timeframe:
  - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of weight-based ribavirin, if indicated **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that their female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
  - Hepatitis B immunization series **OR**
  - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
    - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
    - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
  - Is being treated for human immunodeficiency virus (HIV) **OR**
  - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**

- Medical record documentation of a therapeutic failure on, intolerance to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management **AND**
- If member is greater than or equal to 18 years or weighs greater than or equal to 30 kilograms and the request is for 200/50 mg or 150 mg/37.5 mg strength, medical record documentation of why 400/100 mg tablets cannot be used

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**NOTES:**

1. Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).
2. Treatment naïve, genotype 3 patients with compensated cirrhosis require NS5A RAS Y93H testing for velpatasvir.
3. Sometimes sofosbuvir-velpatasvir is preferred over Mavyret in cases when patients have decompensating features such as portal hypertension, low platelets, encephalopathy, etc. Also, when members are on estrogen-based contraceptives.
4. Sofosbuvir-velpatasvir is pangenotypic, although advised to get Genotype, it is not always necessary and do not have to list this in denial rationale.
5. Per the prescribing information, treatment duration for liver or kidney transplant recipients is 12 weeks. Please refer to guidelines at www.hcvguidelines/org.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, if request is for sofosbuvir/velpatasvir 400/100 include generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tablets: one (1) tablet per day, 28 day supply per fill
  - 150/37.5 mg packets: one (1) packet per day, 28 day supply per fill
  - 200/50 mg packets: two (2) packets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** According to IDSA/AASLD Guidelines (longer treatment duration is recommended when ribavirin ineligible)

| Geisinger | POLICY NUMBER: 434.0 |
|---|---|
| POLICY AND PROCEDURE<br>PHARMACY<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Epclusa and Sofosbuvir/Velpatasvir |

**APPROVAL LANGUAGE:** Meets criteria, auth x (?) weeks, RX count= (?), (28 day supply/fill), generic only [when applicable]. QL: 1 tab/day (QL for LETTER only)

If a formulary exception is approved Epclusa or sofosbuvir/velpatasvir will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Mavyret*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/21/16
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 6/2/17 – removed fibrosis/liver manifestations requirement, added METAVIR scoring.
Revised: 10/10/17 – changed AND to OR after regimen approved by FDA or compendia
Revised: 11/27/17 – updated failure to specifically Mavyret, updated FA, updated signature
Revised: 1/18/18 – updated age format & FA, removed prescriber, added Hep B & HIV criteria
Revised: 1/22/18 – added Hep B vaccination series
Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS
Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
Revised: 3/1/19 – annual review, defined abbr.

Revised: 7/23/19 – added TPA COE exclusion, renamed to generic
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/29/20 – updated age to 6 years and added weight, updated ribavirin to weight based, removed eGFR requirement, updated auth duration to guideline based
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, removed St Lukes & AtlantiCare, updated QL statement, clarified policy to Epclusa 200/50 and generic 400/100
Revised: 11/23/21 – removed strengths from policy title etc., updated age to 3 years, added proper weight based dosing, added criteria requiring 400/100 tablets, added NS5A RAS Y93H note, updated to GPI-14, added QL for 100/50 tabs and packets, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 7/25/23 – removed genotype criterion, prior treatment criterion, generic Harvoni from FA; updated diagnosis criterion, METAVIR scoring criterion, baseline labs within 6 months, HCV RNA within reasonable timeframe, notes, signature title; added approval language; moved concurrent ribavirin criterion, criterion for use of 200/50 or 150/37.5
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 435.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Bevespi Aerosphere**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bevespi Aerosphere for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Bevespi Aerosphere may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Anoro Ellipta

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved Bevespi Aerosphere will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

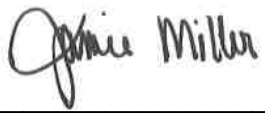
**FORMULARY ALTERNATIVES:**

Anoro Ellipta, fluticasone/salmeterol, Wixela Inhub, Atrovent, Breo Ellipta, Incruse Ellipta, Serevent Diskus, Spiriva, Trelegy Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 435.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Bevespi Aerosphere** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/22/16 |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 436.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Relistor Tablets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Relistor tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Relistor Tablets may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment **AND**
- Medical record documentation of opioid-induced constipation **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Movantik

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day

If a formulary exception is approved Relistor Tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

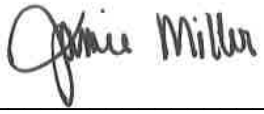
**FORMULARY ALTERNATIVES:**

lubiprostone, Movantik

| Geisinger | POLICY NUMBER: 436.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Relistor Tablets |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/22/16 |
| Reviewed: | 3/1/17 – annual review |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 4/6/18 – updated cancer diagnosis criteria to include prior cancer |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Amitiza to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 437.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ocaliva**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ocaliva for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Ocaliva may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of primary biliary cholangitis (primary biliary cirrhosis) **AND**
- Medical record documentation that Ocaliva is prescribed by a board-certified gastroenterologist, hepatologist, or liver transplant specialist **AND**
- Medical record documentation that Ocaliva is not being used in members with complete biliary obstruction **AND**
    - Medical record documentation of contraindication to or intolerance to UDCA (ursodiol tablets, Urso Forte, or Urso 250) **OR**
    - Medical record documentation of inadequate biochemical response* to an appropriate dose** of UDCA (ursodiol tablets, Urso Forte, or Urso 250) for at least 1 year **AND** that Ocaliva will be prescribed in combination with UDCA

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: one (1) tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will be for a period of six (6) months. The following documentation is required for reauthorization:

- Medical record documentation of monitoring liver function tests, including alkaline phosphatase and bilirubin **AND**
- Medical record documentation of high density lipoprotein-cholesterol (HDL-C) **AND**

- Medical record documentation of a positive response to Ocaliva based on reduction in alkaline phosphatase and bilirubin

If approved, reauthorization will be for one (1) year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement of primary biliary cholangitis defined by alkaline phosphatase and bilirubin levels.

***Note**: Inadequate response: ALP greater than or equal to 1.67 times the upper limit of normal (ULN) and/or if total bilirubin was between 1 and 2 times the ULN.

ULN for females: ALP is 118 U/L and bilirubin is 1.1 mg/dL.
ULN for males: ALP is 124 U/L and bilirubin is 1.5 mg/dL.

****Note**: Appropriate dose of UDCA: 13 to 15 mg/kg/day in 2 to 4 divided doses.

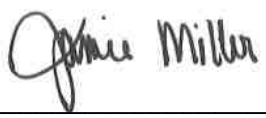
If a formulary exception is approved Ocaliva will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
ursodiol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 437.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ocaliva**

| | |
|---|---|
| Devised: | 11/22/16 |
| Revised: | 1/25/17 – corrected typo in policy section |
| Revised: | 3/1/17 – annual review, defined abbreviations in criteria |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria, added DS limit |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 439.0**

**SECTION: Commercial Drug**
**SUBJECT: Emverm**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Emverm for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Emverm may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of at least one of the following: *Ancylostoma duodenale* or *Necator americanus* (hookworms), *Ascaris lumbricoides* (roundworms), *Enterobius vermicularis* (pinworms), or *Trichuris trichiura* (whipworms)

**QUANTITY LIMIT:**

- *Enterobius vermicularis* (pinworms): two fills of 1 tablet each within 30 days
- All other Food and Drug Administration approved indications: two fills of 6 tablets each within 30 days

If a formulary exception is approved Emverm will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

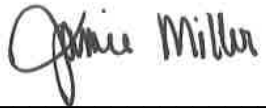
**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 439.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Emverm |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/24/17 |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 440.0**

**SECTION: Commercial Drug**
**SUBJECT: Aspirin/Omeprazole**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for aspirin/omeprazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of aspirin/omeprazole may be made for members who meet the following criteria:

- Medical record documentation of aspirin, component of aspirin/omeprazole, being used for secondary prevention of cardiovascular and/or cerebrovascular events as evident by one of the following:
  - History of ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
  - Previous myocardial infarction or unstable angina pectoris
  - Diagnosis of chronic stable angina pectoris
  - History of prior revascularization procedure (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) when there is a pre-existing condition for which aspirin is already indicated **AND**
- Medical record documentation of risk of developing aspirin associated gastric ulcers as evident by one of the following:
  - Medical record documentation of age greater than or equal to 55 years
  - Medical record documentation indicating a history of gastric ulcers **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to omeprazole, pantoprazole, lansoprazole, **AND** rabeprazole with concurrent use of aspirin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: one (1) tablet per day

If a formulary exception is approved aspirin/omeprazole will be paid for under the member's prescription drug benefit.

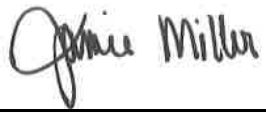
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole, aspirin 81 mg

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/27/17 |
| Revised: | 3/1/18 – annual review, updated signature, updated age & ulcer history criteria |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Yosprala to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 441.0**

**SECTION: Commercial Drug**
**SUBJECT: GoNitro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for GoNitro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of GoNitro may be made for members who meet the following criteria:

- Medical record documentation of a reason why the patient cannot use nitroglycerin sublingual tablets **AND** nitroglycerin translingual spray

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved GoNitro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

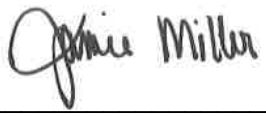
**FORMULARY ALTERNATIVES:**

nitroglycerin sublingual tablets, nitroglycerin translingual spray

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 441.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: GoNitro |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/24/17 |
| Revised: | 3/1/18 – annual review, updated signature, corrected spelling of GoNitro |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/7/22 – corrected policy number typo |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 442.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Rubraca**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rubraca for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Rubraca may be made for members who meet the following criteria:

**Ovarian Cancer**

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer **AND** medical record documentation of Rubraca being used as maintenance treatment after a complete or partial response to platinum-based chemotherapy **OR**
- Medical record documentation of a diagnosis of a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer **AND** medical record documentation of Rubraca being used as maintenance treatment after a complete or partial response to platinum-based chemotherapy

**Prostate Cancer**

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of prior treatment with androgen-receptor directed therapy and a taxane-based chemotherapy **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: four (4) tablets per day, 30 day supply per fill

**NOTE**: For Ovarian Cancer, the Food and Drug Administration approved test is BRACAnalysis CDx, FoundationOne CDx, FoundationFocus CDxBRCA Assay (see http://www.fda.gov/CompanionDiagnostics)

**RE-AUTHORIZATION CRITERIA:** Rubraca is configured as a prior authorization for new starts only. Rubraca will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Rubraca will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

For Breast Cancer: Lynparza*

*prior authorization required

Geisinger

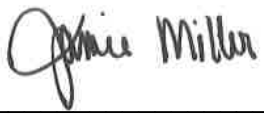
**POLICY NUMBER: 442.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Rubraca**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/24/17 |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria |
| Revised: | 12/28/18 – added recurrent epithelial ovarian, fallopian tube, or primary peritoneal indication, updated deleterious BRCA mutation to include epithelial ovarian, fallopian tube, or primary peritoneal, updated note |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – added prostate cancer indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 7/20/22 – deleted deleterious BRCA mutation ovarian, fallopian tube, or primary peritoneal CA from Ovarian CA section |
| Revised: | 3/1/23 – annual review; added BRCA mutated indication to ovarian CA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 443.0**

**SECTION: Commercial Drug**
**SUBJECT: Nuedexta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuedexta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Nuedexta may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of pseudobulbar affect (PBA)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: two (2) capsules per day

If a formulary exception is approved Nuedexta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

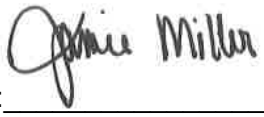
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 443.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Nuedexta** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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|---|---|
| Devised: | 3/27/18 |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 444.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: ProAir Digihaler and ProAir Respiclick**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ProAir Digihaler and ProAir Respiclick for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of ProAir Digihaler and ProAir Respiclick may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to albuterol HFA

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved ProAir Digihaler or ProAir Respiclick will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

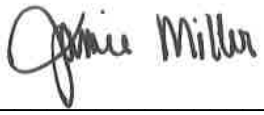
**FORMULARY ALTERNATIVES:**

albuterol HFA

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 444.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: ProAir Digihaler and ProAir Respiclick** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/27/18 |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/15/19 – updated policy name to generic |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 10/12/20 – updated to ProAir Digihaler/Respiclick, updated Ventolin to albuterol (generic now form.) |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 445.0**

**SECTION: Commercial Drug**
**SUBJECT: Non-Preferred Diabetic Testing Supplies**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for non-preferred diabetic testing supplies for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of non-preferred diabetic testing supplies may be made for members who meet the following criteria:

- Medical record documentation of Type I, Type II, or gestational diabetes **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on a LifeScan product **OR**
- Medical record documentation of use of an insulin pump requiring a specific monitor brand **OR**
- Medical record documentation of the requirement of a feature not available from a LifeScan Product (i.e., speech capability)

**MEDISPAN AUTHORIZATION LEVEL:** NDC-9

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 200 strips per 30 days

If a formulary exception is approved the non-preferred diabetic testing supplies will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

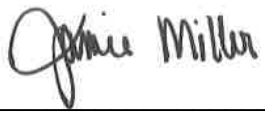
**FORMULARY ALTERNATIVES:**

One Touch Ultra 2, One Touch UltraMini, One Touch Verio, One Touch Verio IQ, One Touch Verio Sync

| Geisinger | POLICY NUMBER: 445.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Non-Preferred Diabetic Testing Supplies |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/27/17 |
| Revised: | 3/1/18 – annual review, updated signature |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, added test strip QL |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; renamed policy |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 446.0**

**SECTION: Commercial Drug**
**SUBJECT: Emflaza**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Emflaza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Emflaza may be made for members who meet the following criteria:

- Medical record documentation that Emflaza is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of interdisciplinary team involvement including, but not limited to, neurology, pulmonology, and cardiology **AND**
- Medical record documentation of a diagnosis of Duchenne muscular dystrophy (DMD), confirmed by genetic testing **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to prednisone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 6 mg tablet: 2 tablets per day
  - 18 mg tablet: 1 tablet per day
  - 30 mg tablet: 2 tablets per day
  - 36 mg tablet: no quantity limit
  - 22.75 mg/mL: no quantity limit

**NOTE:** Emflaza tablets may be crushed and served immediately after mixing with applesauce.

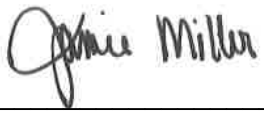
If a formulary exception is approved Emflaza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
prednisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/2/17 |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note, removed QL note |
| Revised: | 11/20/19 – updated age criteria to 2 years and older |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 447.0**

**SECTION: Commercial Drug**
**SUBJECT: Kisqali**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kisqali for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Kisqali may be made for members who meet the following criteria:

**Kisqali as Initial Endocrine Therapy**

- Medical record documentation that Kisqali is prescribed by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2-negative, advanced or metastatic breast cancer **AND**
- Medical record documentation that Kisqali is being prescribed as initial endocrine therapy **AND**
- Medical record documentation that Kisqali will be used in combination with an aromatase inhibitor or fulvestrant **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of postmenopausal status **OR**
  - Medical record documentation of pre/perimenopausal status or member is male **AND** that member will be treated with a luteinizing hormone-releasing hormone (LHRH) agonist AND

**Kisqali Following Disease Progression on Endocrine Therapy**

- Medical record documentation that Kisqali is prescribed by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2-negative, advanced or metastatic breast cancer **AND**

- Medical record documentation that Kisqali is being prescribed after disease progression following endocrine therapy **AND**
- Medical record documentation that Kisqali will be used in combination with fulvestrant **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of postmenopausal status **OR**
    - Medical record documentation of pre/perimenopausal status **AND** that member will be treated with a luteinizing hormone-releasing hormone (LHRH) agonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (must include 2153107050B7 & 2199000260B7), number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - Kisqali 200 mg per day: 21 tablets per 28 days
    - Kisqali 400 mg per day: 42 tablets per 28 days
    - Kisqali 600 mg per day: 63 tablets per 28 days
    - Kisqali/Femara 200 mg per day co-pack: 49 tablets per 28 days
    - Kisqali/Femara 400 mg per day co-pack: 70 tablets per 28 days
    - Kisqali/Femara 600 mg per day co-pack: 91 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Kisqali is configured as a prior authorization for new starts only. Kisqali will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Kisqali will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 447.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Kisqali |

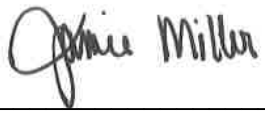
**FORMULARY ALTERNATIVES:**

Ibrance*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

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|---|---|
| Devised: | 6/2/17 |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria |
| Revised: | 11/28/18 – added pre/perimenopausal, added combo with fulvestrant, split indications to initial endocrine vs. following disease progression, added QL statement |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, added coverage for males for initial therapy |
| Revised: | 4/6/22 – removed ovarian ablation/suppression |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 448.0**

**SECTION: Commercial Drug**
**SUBJECT: Topiramate Extended Release Sprinkle Capsules (generic Qudexy)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for topiramate extended release sprinkle capsules (generic Qudexy) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of topiramate extended release sprinkle capsules (generic Qudexy) may be made for members who meet the following criteria:

**Seizure Disorders**

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut Syndrome **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication three formulary alternatives, one of which must be topiramate immediate release

**Migraine Headache Prophylaxis**

- Medical record documentation of use for prophylaxis of migraine headaches **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, topiramate extended release sprinkle capsules (generic Qudexy) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Seizure Disorders**: carbamazepine, divalproex, felbamate, valproic acid, topiramate immediate release, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, zonisamide, gabapentin, tiagabine, phenobarbital, pregabalin

**Migraine Prophylaxis**: topiramate immediate release, propranolol, timolol, divalproex delayed release, divalproex extended release, amitriptyline, atenolol, metoprolol, nadolol, venlafaxine, sodium valproate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/2/17 |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/13/19 – updated formulary alternatives |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated to clarify policy is for generic Qudexy |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 449.0**

**SECTION: Commercial Drug**
**SUBJECT: Sevelamer HCl (generic Renagel)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sevelamer HCl (generic Renagel) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of sevelamer HCl (generic Renagel) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease (CKD) on dialysis **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on calcium acetate **AND** sevelamer carbonate (generic Renvela) **AND** lanthanum carbonate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, sevelamer HCl (generic Renagel) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

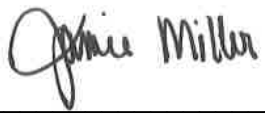
**FORMULARY ALTERNATIVES:**

calcium acetate, sevelamer carbonate (generic Renvela), lanthanum carbonate, Fosrenol powder packet

| Geisinger | POLICY NUMBER: 449.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Sevelamer HCl<br>(generic Renagel) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/2/17 |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 4/5/18 – updated FA criteria to generic products, updated FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 11/21/19 – updated Renagel to generic sevelamer HCl |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated FA; clarified failure is generic Renvela |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 450.0**

**SECTION: Commercial Drug**
**SUBJECT: Soliqua**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Soliqua for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Soliqua may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xultophy **AND**
- Medical record documentation that the dose of Soliqua is being prescribed at a minimum of 15 units (15 units insulin glargine/5 mcg lixisenatide) and no more than 60 units (60 units insulin glargine/20 mcg lixisenatide)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.6 mL per day

If an exception is made, Soliqua will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

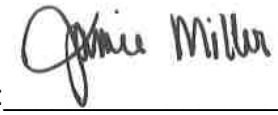
Xultophy*

*step therapy required

| Geisinger | **POLICY NUMBER: 450.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Soliqua** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/2/17 |
| Revised: | 3/1/18 – annual review, updated signature, updated FA |
| Revised: | 3/1/19 – annual review, updated FA |
| Revised: | 7/23/19 – added QL |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 451.0**

**SECTION: Commercial Drug**
**SUBJECT: Adlyxin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adlyxin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Adlyxin may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin, Victoza **AND** either Ozempic or Rybelsus

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.2 mL per day

If an exception is made, Adlyxin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

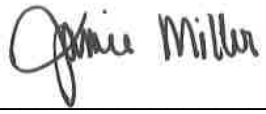
metformin, Ozempic*, Victoza*, Rybelsus*, Trulicity*

*prior authorization required

| Geisinger | POLICY NUMBER: 451.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Adlyxin |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/2/17 |
| Revised: | 1/17/18 – updated failure to Ozempic from Tanzeum, updated FA, updated QL to daily limit, updated signature |
| Revised: | 3/1/18 – annual review, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 1/28/20 – added failure of Rybelsus, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, added metformin to FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature; updated to GPI-12 |

Geisinger

**POLICY NUMBER: 452.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xultophy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xultophy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xultophy may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of a formulary GLP-1 agonist **OR** a formulary long-acting basal insulin product, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary GLP-1 agonist **OR** one formulary long-acting basal insulin product

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 15 mL per 30 days

If an exception is made, Xultophy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Ozempic*, Victoza*, Rybelsus*, Trulicity*, Lantus, Toujeo, Tresiba, Levemir

*prior authorization required

| Geisinger | POLICY NUMBER: 452.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xultophy |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/2/17 |
| Revised: | 3/1/18 – annual review, updated signature, added ST language, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 7/23/19 – added “long-acting” to basal insulin requirement |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, added Rybelsus to FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated FA |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 453.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Alunbrig**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alunbrig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Alunbrig may be made for members who meet the following criteria:

- Medical record documentation that Alunbrig is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of ALK-positive, metastatic non-small cell lung cancer

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 30 mg tablet: 2 tablets per day, 30 day supply per fill
  - 90 mg, 180 mg, and Starter Pack: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Alunbrig is configured as a prior authorization for new starts only. Alunbrig will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Alunbrig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

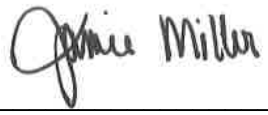
**FORMULARY ALTERNATIVES:**

Xalkori*, Zykadia*, Alecensa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/8/17 |
| Revised: | 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – removed failure of Xalkori |
| Revised: | 10/12/20 – updated QL |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 454.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Rydapt**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rydapt for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Rydapt may be made for members who meet the following criteria:

**AML**

- Medical record documentation that Rydapt is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Rydapt will be administered in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

**NOTE:** Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

**ASM / SM-AHN / MCL**

- Medical record documentation that Rydapt is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation of a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis associated with hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:**

- AML
  - In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and 56 capsules per 21 days (max quantity 56, min/max day supply 21. *QL must be entered within the authorization.*
  - QL FOR LETTER: 56 capsules per 21 days
- ASM / SM-AHN / MCL:
  - *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
  - QL FOR LETTER: 224 capsules per 28 days

**RE-AUTHORIZATION CRITERIA:** Rydapt is configured as a prior authorization for new starts only. Rydapt will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Rydapt will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ASM: imatinib

| Geisinger | POLICY NUMBER: 454.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Rydapt |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/8/17 |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 5/24/19 – updated ASM/SM-AHN/MCL QL |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated auth entry parameters |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 455.0**

**SECTION: Commercial Drug**
**SUBJECT: Zejula**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zejula for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Zejula may be made for members who meet the following criteria:

**First-line Maintenance Treatment of Advanced Ovarian Cancer**

- Medical record documentation that Zejula is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation that Zejula is being used as maintenance treatment **AND**
- Medical record documentation that member is in complete or partial response to first-line platinum-based chemotherapy **AND**
- Medical record documentation that Zejula is being given at a dosage consistence with Food and Drug Administration (FDA)-approved labeling*

**Maintenance Treatment of Recurrent Germline BRCA-Mutated Ovarian Cancer**

- Medical record documentation that Zejula is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation that Zejula is being used as maintenance treatment **AND**
- Medical record documentation of receiving at least 2 prior platinum-containing regimens **AND**
- Medical record documentation of a complete or partial response to the most recent platinum based chemotherapy **AND**
- Medical record documentation that Zejula is being given at a dosage consistent with Food and Drug Administration (FDA)-approved labeling (300mg once daily)

***NOTE:** For the first-line treatment of advanced ovarian cancer:

- For patient weight less than 77 kg (170 lbs) **OR** with a platelet count of less than 150,000/µL, the recommended dose is 200 mg (two 100-mg capsules taken orally once daily).
- For patient weight greater than or equal to 77 kg (170 lbs) **AND** who have a platelet count greater than or equal to 150,000/µL the recommended dose is 300 mg (three 100-mg capsules) taken orally once daily.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Zejula is configured as a prior authorization for new starts only. Zejula will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Zejula will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

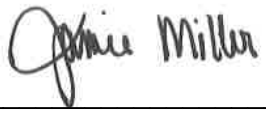
**FORMULARY ALTERNATIVES:**

Lynparza*, Rubraca*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/8/17 |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 1/28/20 – added advanced ovarian, fallopian tube, and primary peritoneal cancer indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 7/29/20 – reorganized criteria for better usability, added advanced ovarian after complete/partial response to platinum therapy indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; added first-line to platinum criterion of advanced ovarian CA indication; deleted section for failure of 3 or more treatments; edits BRCA-mutated section to include deleterious BRCA updated; added 2 prior platinum regimens; added dosage criterion; added most recent to platinum response criterion; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 456.0**

**SECTION: Commercial Drug**
**SUBJECT: Eucrisa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Eucrisa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Eucrisa may be made for members who meet the following criteria:

- Medical record documentation that Eucrisa is prescribed by or in consultation with a dermatologist **AND**
- Medical record documentation of a diagnosis of mild to moderate atopic dermatitis **AND**
- **For members 2 years of age and older:** Medical record documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on at least two (2) formulary topical corticosteroids unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) or (b) member is less than 15 years of age

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved Eucrisa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

tacrolimus ointment

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

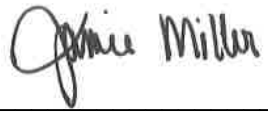
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 456.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Eucrisa** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/8/17 |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 10/12/20 – removed age criteria, updated to failure of tacrolimus only if 2 years or older, removed "between 2 and" from failure of steroids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signture |

| Geisinger | POLICY NUMBER: 457.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Dupixent** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dupixent for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Dupixent may be made for members who meet the following criteria:

**Atopic Dermatitis**

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 6 months **AND**
- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure* on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
    - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable (use on sensitive areas, age between 2 and 15 years): Therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

***NOTES:** Therapeutic failure is defined as an inability to achieve and maintain remission of low to mild disease activity.

Atopic Dermatitis
Dosage in Adults (2.3):
Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W).

Dosage in Pediatric Patients 6 Months to 5 Years of Age (2.3):

| Body Weight | Initial and Subsequent Dosage |
|---|---|
| 5 to less than 15 kg | 200 mg (one 200 mg injection) every 4 weeks (Q4W) |
| 15 to less than 30 kg | 300 mg (one 300 mg injection) every 4 weeks (Q4W) |

Dosage in Pediatric Patients 6 Years to 17 Years of Age (2.3):

| Body Weight | Initial Loading Dose | Subsequent Dosage[a] |
|---|---|---|
| 15 to less than 30 kg | 600 mg (two 300 mg injections) | 300 mg Q4W |
| 30 to less than 60 kg | 400 mg (two 200 mg injections) | 200 mg Q2W |
| 60 kg or more | 600 mg (two 300 mg injections) | 300 mg Q2W |

[a] Q2W – every other week; Q4W – every 4 weeks

**AUTHORIZATION DURATION**: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT**

- **Initial Approval**
  - 600 mg once, followed by 300 mg every other week
    1. In NCRx: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
    2. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
       - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
  - 600 mg once, followed by 300 mg every four weeks

1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
2. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, and max quantity dispensed 2 with a start date 1 day after the loading dose ends for the remainder of the authorization.
    - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 2 mL per 28 days

- 400 mg once, followed by 200 mg every other week
    1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity dispensed 4.56, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
    2. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, and max quantity dispensed 2.28 with a start date 1 day after the loading dose ends for the remainder of the authorization.
        - QL FOR LETTER: Loading dose: 4.56 mL per 42 days, Maintenance dose: 2.28 mL per 28 days
- 200 mg every four weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 2.28, minimum day supply 56, and maximum day supply 56.
        - QL FOR LETTER: 2.28 mL per 56 days
- 300 mg every four weeks
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 4, minimum day supply 56, and maximum day supply 56.
        - QL FOR LETTER: 4 mL per 28 days

- **Renewal –**
    - 300 mg every other week
        1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, and max quantity dispensed 4.
            - QL FOR LETTER: 4 mL per 28 days
    - 300 mg every four weeks
        1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 4, minimum day supply 56, and maximum day supply 56.
            - QL FOR LETTER: 4 mL per 28 days
    - 200 mg every other week

1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 2.28.
    - QL FOR LETTER: 2.28 mL per 28 days

- 200 mg every four weeks
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 2.28, minimum day supply 56, and maximum day supply 56.
        - QL FOR LETTER: 2.28 mL per 56 days

****Topical Corticosteroid Potency Chart:**

| Potency Group | Corticosteroid | Vehicle/Form | Strength |
|---|---|---|---|
| **Super-high Potency** | Betamethasone dipropionate, augmented | Ointment, Lotion, Gel | 0.05% |
| | Clobetasol propionate | Ointment, Cream, Gel, Lotion Foam, Shampoo, Solution, Spray | 0.05% |
| | Fluocinonide | Cream | 0.1% |
| | Halobetasol propionate | Ointment, Cream, Lotion | 0.05% |
| **High Potency** | Amcinonide | Ointment | 0.1% |
| | Betamethasone dipropionate | Ointment, Cream | 0.05% |
| | Desoximetasone | Cream | 0.05% |
| | Diflorasone diacetate | Cream | 0.05% |
| | Fluocinonide | Cream | 0.05% |
| | Fluticasone propionate | Ointment | 0.005% |
| | Mometasone furoate | Ointment | 0.1% |
| | Triamcinolone acetonide | Ointment, Cream | 0.5% |
| **Medium Potency** | Betamethasone dipropionate | Spray | 0.05% |
| | Clocortolone pivalate | Cream | 0.1% |
| | Fluocinolone acetonide | Ointment | 0.025% |
| | Flurandrenolide | Ointment | 0.05% |
| | Hydrocortisone valerate | Ointment | 0.2% |
| | Mometasone furoate | Cream, Lotion, Solution | 0.1% |
| | Triamcinolone acetonide | Cream, Ointment | 0.1% |
| | | Aerosol Spray | 0.2% |
| **Lower-mid Potency** | Betamethasone dipropionate | Lotion | 0.05% |
| | Betamethasone valerate | Cream | 0.1% |
| | Desonide | Ointment, Gel | 0.05% |
| | Fluocinolone acetonide | Cream | 0.025% |
| | Flurandrenolide | Cream, Lotion | 0.05% |
| | Fluticasone propionate | Cream, Lotion | 0.05% |
| | Hydrocortisone butyrate | Ointment, Cream, Lotion, Solution | 0.1% |
| | Hydrocortisone probutate | Cream | 0.1% |
| | Hydrocortisone valerate | Cream | 0.2% |
| | Prednicarbate | Cream, Ointment | 0.1% |
| | Triamcinolone acetonide | Lotion | 0.1% |
| | | Ointment | 0.025% |
| **Low Potency** | Alclometasone dipropionate | Ointment, Cream | 0.05% |
| | Betamethasone valerate | Lotion | 0.1% |
| | Desonide | Cream, Lotion, Foam | 0.5% |

| | | | |
|---|---|---|---|
| | Fluocinolone acetonide | Cream, Solution, Shampoo, Oil | 0.01% |
| | Triamcinolone acetonide | Cream, Lotion | 0.025% |
| **Least Potent** | Hydrocortisone (base) | Ointment, Cream, Lotion, Solution, Spray, Foam | 0.5%, 1%, 2%, 2.5% |

**FORMULARY ALTERNATIVES:**

Systemic Therapies:
azathioprine, cyclosporine, methotrexate, mycophenolate

Topical Therapies:
Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*
Eucrisa*
**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

*prior authorization required

**Asthma**

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
  - A diagnosis of moderate to severe eosinophilic asthma **AND** a blood eosinophilic count greater than or equal to 150 cells/microL **OR**
  - A diagnosis of oral corticosteroid dependent asthma **AND**
- Medical record documentation that Dupixent will be used as an add-on maintenance treatment **AND**
- Medical record documentation of one of the following:
  - Contraindication, intolerance to, or poorly (not well) controlled symptoms despite at least a 3-month trial of: maximally tolerated inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
  - One exacerbation in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy or intolerance to inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that Dupixent will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Xolair, Fasenra, Nucala, Cinqair, or Tezspire) **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

**Measures of Disease Severity**

| Measure | **Not Well Controlled** | **Very Poorly Controlled** |
|---|---|---|
| Symptoms | > 2 days per week | Throughout the day |
| Nighttime awakenings | 1-3x/week | > 4x/week |
| Interference with normal activity | Some limitation | Extremely limited |
| SABA use for symptom control (not to prevent exercise-induced bronchospasm) | > 2 days/week | Several times per day |
| FEV1 (% predicted) or peak flow (% personal best) | 60-80% | < 60% |
| Asthma Control Test (ACT) Score | 16-19 | < 15 |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**#NOTE:**

Asthma

Dosage in Adult and Pediatric Patients 12 Years and Older

| Initial Loading Dose | Subsequent Dose |
|---|---|
| 400 mg (two 200 mg injections) | 200 mg every 2 weeks (Q2W) |
| or | |
| 600 mg (two 300 mg injections) | 300 mg every 2 weeks (Q2W) |
| **Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis** | |
| 600 mg (two 300 mg injections) | 300 mg every 2 weeks (Q2W) |

Dosage in Pediatric Patients 6 to 11 Years of Age

| Body Weight | Initial Dose and Subsequent Doses |
|---|---|
| 15 to less than 30 kg | 100 mg every other week (Q2W)<br>or<br>300 mg every four weeks (Q4W) |
| ≥30 kg | 200 mg every other week (Q2W) |

**QUANTITY LIMIT**

- **Initial Approval**
  - 600 mg once, followed by 300 mg every other week
    1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
    2. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
       - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
  - 400 mg once, followed by 200 mg every other week
    1. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity dispensed 4.56, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
    2. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, and max quantity dispensed 2.28 with a start date 1 day after the loading dose ends for the remainder of the authorization.
       - QL FOR LETTER: Loading dose: 4.56 mL per 42 days, Maintenance dose: 2.28 mL per 28 days

- 300 mg every four weeks (no loading dose required)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max quantity dispensed 4, minimum day supply 56, and maximum day supply 56.
        - QL FOR LETTER: 4 mL per 28 days
- 100 mg every other week (no loading dose required)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 1.34
        - QL FOR LETTER: 1.34 mL per 28 days
- 200 mg every other week (no loading dose required)
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 2.28
        - QL FOR LETTER: 2.28 mL per 28 days

- **Renewal –**
    - 300 mg every other week
        1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 4
            - QL FOR LETTER: 4 mL per 28 days
    - 300 mg every four weeks
        1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, OUP, DS, max quantity dispensed 4, minimum day supply 56, and maximum day supply 56.
            - QL FOR LETTER: 4 mL per 28 days
    - 200 mg every other week
        1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 2.28
            - QL FOR LETTER: 2.28 mL per 28 days
    - 100 mg every other week
        1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 1.34
            - QL FOR LETTER: 1.34 mL per 28 days

**AUTHORIZATION DURATION**: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**

- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

**FORMULARY ALTERNATIVES:**
Inhaled Therapies: Arnuity Ellipta, Asmanex, Flovent, Pulmicort Flexhaler, QVAR RediHaler, fluticasone/salmeterol, Breo Ellipta, Dulera

Systemic Therapies: prednisone, dexamethasone, methylprednisolone, prednisolone

**Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyposis (CRwNP) **AND**
- Medical record documentation that Dupixent will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

[#]**NOTE:** Recommended dosage for adult patients is 300 mg given every other week. No loading dose is required.

**QUANTITY LIMIT:**

- 300 mg every other week
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 4.
        - QL FOR LETTER: 4 mL per 28 days

**AUTHORIZATION DURATION**: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

**FORMULARY ALTERNATIVES:**
fluticasone propionate, triamcinolone acetonide, mometasone furoate

**Eosinophilic Esophagitis**

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of weight greater than or equal to 40 kilograms **AND**
- Medical record documentation of a diagnosis of eosinophilic esophagitis **AND**
- Medical record documentation of greater than or equal to 15 intraepithelial eosinophils per high-power field (eos/hpf) **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on a proton pump inhibitor **AND**
- Medical record documentation that the member is experiencing chronic symptoms of esophageal dysfunction (for example, dysphagia, food impaction, food refusal, abdominal pain, heartburn, regurgitation, chest pain, odynophagia) **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on a swallowed inhaled respiratory glucocorticoid **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

[#]**NOTE:** Recommended dosage for patients aged 12 years and older is 300 mg given once weekly. No loading dose is required.

**QUANTITY LIMIT**

- 300 mg once weekly
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 8.
        - QL FOR LETTER: 8 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

**FORMULARY ALTERNATIVES:**
Proton pump inhibitors: omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole
Inhaled respiratory glucocorticoids: budesonide inhalation suspension, Flovent HFA

**Prurigo Nodularis**

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or dermatologist A**ND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of prurigo nodularis **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of a failure on a very-high potency topical corticosteroid (for example, clobetasol dipropionate 0.05% ointment) **OR** calcineurin inhibitor (i.e. tacrolimus) if topical corticosteroids are not advisable **OR**
  - Medical record documentation of widespread or recalcitrant disease **AND** contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND** systemic therapy (including methotrexate and/or cyclosporine)

[#]**NOTE:** Recommended dosage for adults is 600 mg once, followed by 300 mg given every other week.

**QUANTITY LIMIT**

- **Initial Approval**
  - 600 mg once, followed by 300 mg every other week
    1. In NCRx: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
    2. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
       - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
- **Renewal**
  - 300 mg every other week
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, and max quantity dispensed 4.
       - QL FOR LETTER: 4 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

**FORMULARY ALTERNATIVES:**
Systemic Therapies: cyclosporine, methotrexate

Topical Therapies: Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*, Eucrisa*

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

*prior authorization required

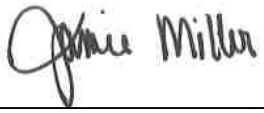
If a formulary exception is approved Dupixent will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 457.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Dupixent** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/8/17 |
| Revised: | 10/4/17 – updated QL from syringes to mL's |
| Revised: | 3/1/18 – annual review, updated signature, updated prescriber criteria |
| Revised: | 10/8/18 – clarified "at least one" systemic failure, added allergist/immunologist |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – added asthma indication, updated FA |
| Revised: | 6/4/19 – added authorization parameters |
| Revised: | 7/12/19 – corrected 200 mg dosage typo in authorization parameters |
| Revised: | 7/23/19 – Atopic dermatitis: decreased age to 12, removed failure of systemic therapy, updated to failure of one steroid, tacrolimus, Eucrisa, and phototherapy |
| Revised: | 11/20/19 – reformatted policy, added CRSwNP indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/17/20 – updated age requirements for atopic dermatitis, moved FA to under each indication |
| Revised: | 1/25/21 – updated atopic dermatitis to failure of steroid or calcineurin inhibitor, added MediSpan approval lever, updated auth duration/QL language |
| Revised: | 3/1/21 – annual review, updated logo, corrected QL's |
| Revised: | 6/15/21 – removed criteria for failure of tacrolimus and Eucrisa for atopic derm. (January P&T) |
| Revised: | 11/23/21 – updated age for asthma to 6, updated asthma QL formatting and added 100 mg dose, updated QL for atopic dermatitis to include 400 mg EOW and 300 mg every 4 week dosing, updated QL entry to account for DS over 28 |
| Revised: | 1/21/22 – updated to GPI-10, updated how QL's are entered, added dosage criterion, added dosing chart |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered |
| Revised: | 4/6/22 – added additional prescribers to CRSwNP, updated age to 6 years for asthma & atopic derm. |
| Revised: | 6/7/22 – updated concurrent biologic criterion in asthma indication |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives in atopic dermatitis section |
| Revised: | 12/22/22 – updated AD age to 6 months; updated note for AD dosing; added QL for 200 mg Q4 weeks and 300 mg Q4 weeks for AD; added eosinophilic esophagitis & prurigo nodularis indications |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 11/1/23 – updated signature title; updated 200 mg & 400 mg every 4 week QL's to allow 56 days |
| Revised: | 3/1/24 – annual review; updated auth entry parameters |

Geisinger

**POLICY NUMBER: 458.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Trulance**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trulance for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Trulance may be made for members who meet the following criteria:

**Chronic Idiopathic Constipation**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic idiopathic constipation **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Linzess **AND** lubiprostone

**Irritable Bowel Syndrome with Constipation (IBS-C)**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of irritable bowel syndrome with constipation (IBS-C) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Linzess

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved Trulance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 458.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Trulance**

**FORMULARY ALTERNATIVES:**
Chronic Idiopathic Constipation: lubiprostone, Linzess
Irritable Bowel Syndrome with Constipation: Linzess

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 8/8/17 |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 8/7/18 – added IBS-C indication, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/18/20 – corrected QL typo |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Amitiza to generic |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 459.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xermelo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xermelo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Xermelo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of carcinoid syndrome diarrhea **AND**
- Medical record documentation of an inadequate response* on a somatostatin analog monotherapy **AND**
- Medical record documentation that Xermelo will be used in combination with a somatostatin analog (i.e., octreotide, Sandostatin LAR Depot, Somatuline Depot)

***NOTE:** In the clinical trials, inadequate response was defined as at least 4 bowel movements per day with 3 months or more of a stable dose of a somatostatin analog.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day

If a formulary exception is approved Xermelo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

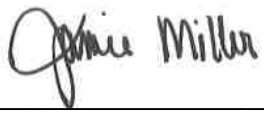
| Geisinger | POLICY NUMBER: 459.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xermelo |

**FORMULARY ALTERNATIVES:**
octreotide, Somatuline Depot*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 8/8/17
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 460.0**

**SECTION: Commercial Drug**
**SUBJECT: Vosevi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vosevi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***HBV*** – Hepatitis B Virus
7. ***HCV*** – Hepatitis C Virus
8. ***HIV*** – Human Immunodeficiency Virus

**PROCEDURE:**

A formulary exception for coverage of Vosevi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis **AND**
- Medical record documentation of METAVIR liver scoring or cirrhosis assessment by a non-invasive test **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation that Vosevi is prescribed by a board-certified gastroenterologist, hepatologist, infectious disease specialist, or transplant specialist **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 6 months:

  - Hepatic function panel
  - Complete blood count including differential
  - Basic metabolic panel **AND**
- Medical record documentation of receiving the following within a reasonable timeframe:
  - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of weight-based ribavirin, if indicated **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that their female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
  - Hepatitis B immunization series **OR**
  - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
    - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
    - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
  - Is being treated for human immunodeficiency virus (HIV) **OR**
  - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**

- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**NOTES:**

1. Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).
2. Vosevi is usually reserved for treatment-experienced patients. It is an IIa recommendation according to the AASLD/IDSA Guidelines which is equivalent to Mavyret + sofosbuvir + ribavirin in most scenarios. Ribavirin is sometimes avoided due to frequent lab work.
3. Guidelines can be referenced at www.hcvguidelines.org.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: one (1) tablet per day, 28 day supply per fill

**AUTHORIZATION DURATION:** 12 weeks **OR** as per Consistent with AASLD/ IDSA Guidelines (12 weeks, 24 weeks) for Treatment Experienced patients

**APPROVAL LANGUAGE:** Meets criteria, auth x (?) weeks, RX count= (?), (28 day supply/fill), generic only [when applicable]. QL: 1 tab/day (QL for LETTER only)

If a formulary exception is approved Vosevi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

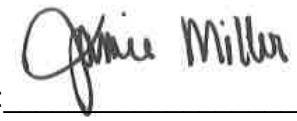
**FORMULARY ALTERNATIVES:**
Mavyret*

*prior authorization required

| Geisinger | POLICY NUMBER: 460.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Vosevi |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/28/17 |
| Revised: | 11/28/17 – updated failure to specifically Mavyret, updated signature |
| Revised: | 1/19/18 – updated age format, removed prescriber, added Hep B & HIV criteria |
| Revised: | 3/1/18 – annual review, updated prescriber criteria & Hep B/HIV criteria to match DHS |
| Revised: | 12/28/18 – added HCV positive transplant indication/FA criteria, added COE |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 7/23/19 – added TPA COE exclusion |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed Atlanticare & St Lukes |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 7/25/23 – removed prior treatment criterion, renal impairment criterion; updated diagnosis criterion, METAVIR scoring criterion, baseline labs within 6 months, HCV RNA within reasonable timeframe, notes, signature title, authorization duration; added approval language, ribavirin criteria |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 461.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Mavyret**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mavyret for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***HBV*** – Hepatitis B Virus
7. ***HCV*** – Hepatitis C Virus
8. ***HIV*** – Human Immunodeficiency Virus

**PROCEDURE:**

A formulary exception for coverage of Mavyret may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years **AND**
- If member is under the age or 12 years or weighs less than 45 kilograms, medical record documentation that proper weight-based dosing is prescribed **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) **AND**
- Medical record documentation of METAVIR liver scoring or cirrhosis assessment by a non-invasive test **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 6 months:
    - Hepatic function panel

    - Complete blood count including differential
    - Basic metabolic panel **AND**
- Medical record documentation of receiving the following within a reasonable timeframe:
    - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
    - Hepatitis B immunization series **OR**
    - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis N virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
        - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
        - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
    - Is being treated for human immunodeficiency virus (HIV) **OR**
    - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management **AND**
- If member is greater than or equal to 12 years of age or weighs greater than or equal to 45 kilograms and the request is for packets, medical record documentation of why tablets cannot be used

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor

**NOTES:**

1. Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).
2. Mavyret is pangenotypic, although advised to get Genotype, it is not always necessary and do not have to list this in denial rationale.
3. Per the prescribing information, treatment duration for liver or kidney transplant recipients is 12 weeks. Geisinger has been treating kidney transplant recipients for 8 weeks with success. Please refer to guidelines at www.hcvguidelines.org.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Tablets: three (3) tablets per day, 28 day supply per fill
  - Packets: six (6) packets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** 8, 12, or 16 weeks consistent with current AASLD/IDSA guidelines or Food and Drug Administration (FDA) recommendations

**APPROVAL LANGUAGE:** Meets criteria, auth x (?) weeks, RX count= (?), (28 day supply/fill), QL: 3 tabs/day (QL for LETTER only)

If a formulary exception is approved Mavyret will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 461.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Mavyret** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/28/17 |
| Revised: | 1/19/18 – updated age format & sig., removed prescriber, added Hep B & HIV criteria |
| Revised: | 1/24/18 – added Hep B immunization series bullet |
| Revised: | 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS |
| Revised: | 12/28/18 – added HCV positive transplant indication, added COE |
| Revised: | 2/6/19 – added liver/kidney transplant indication and corresponding note |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 7/23/19 – added TPA COE exclusion, corrected typo |
| Revised: | 10/1/19 – updated age to 12 years or weight greater than 45 kg |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed Atlanticare & St. Lukes |
| Revised: | 11/23/21 – updated age to 3 years, added proper weight based dosing, added requirement to use tablets, added QL for packets |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; defined abbreviations |
| Revised: | 7/25/23 – removed genotype criterion & prior treatment criterion; updated diagnosis criterion, METAVIR scoring criterion, baseline labs within 6 months, HCV RNA within reasonable timeframe, notes, signature title; added approval language |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 462.0**

**SECTION: Commercial Drug**
**SUBJECT: Idhifa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Idhifa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Idhifa may be made for members who meet the following criteria:

- Medical record documentation that Idhifa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia **AND**
- Medical record documentation of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a Food and Drug Administration (FDA) approved test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**NOTE:** The Food and Drug Administration (FDA) approved test is Abbott RealT*ime*™ IDH2 assay.

**RE-AUTHORIZATION CRITERIA:** Idhifa is configured as a prior authorization for new starts only. Idhifa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Idhifa will be paid for under the member's prescription drug benefit.

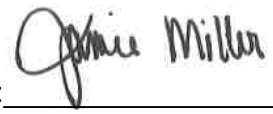
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/28/17
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber & age criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Reviewed: 3/1/23 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 462.0**

**SECTION: Commercial Drug**
**SUBJECT: Idhifa**

Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 463.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nerlynx**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nerlynx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Nerlynx may be made for members who meet the following criteria:

- Medical record documentation that Nerlynx is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- One of the following:
  - Medical record documentation of a diagnosis of early stage (stages I-IIIA) breast cancer **AND**
  - Medical record documentation of HER-2 overexpression/amplification **AND**
  - Medical record documentation of prior treatment with trastuzumab-based therapy

**OR**

  - Medical record documentation of a diagnosis of advanced or metastatic HER2-positive breast cancer **AND**
  - Medical record documentation of two or more prior anti-HER2 based regimens given in the metastatic setting **AND**
  - Medical record documentation that Nerlynx will be used in combination with capecitabine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets per day, up to a 30 day supply per fill

**AUTHORIZATION DURATION**:

- Early Stage Breast Cancer: One time, 12 month authorization
- Advanced or Metastatic Breast Cancer: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**NOTE:** The Food and Drug Administration (FDA) approved dosing schedule only approves the use of Nerlynx for 1 year following adjuvant trastuzumab therapy.

If a formulary exception is approved Nerlynx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

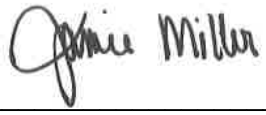
lapatinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 463.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Nerlynx** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/28/17 |
| Revised: | 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/4/20 – added advanced/metastatic HER2-positive breast cancer indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 464.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Austedo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Austedo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Austedo may be made for members who meet the following criteria:

**Huntington's Disease**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Austedo is prescribed by, or in consultation with, a neurologist or movement disorder specialist **AND**
- Medical record documentation of a diagnosis of Huntington's Disease **AND**
- Medical record documentation of symptoms of chorea **AND**
- Medical record documentation of that patient's baseline Total Maximal Chorea Score prior to initiating therapy **AND**
- One of the following:
  - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
  - For all others: Medical record documentation of a mental health evaluation performed by the prescriber **AND**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to tetrabenazine

**Tardive Dyskinesia**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Austedo is prescribed by, or in consultation with, a psychiatrist or neurologist **AND**
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
  - Moderate to severe abnormal body movement (AIMS score 3 or 4) in greater than or equal to 1 body area **OR**

    - Mild abnormal body movements (AIMS score 1 or 2) in greater than or equal to 2 body areas **AND**
- Medical record documentation that the member was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the member's baseline AIMS score prior to initiating therapy **AND**
- One of the following:
    - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
    - For all others: Medical record documentation of a mental health evaluation performed by the prescriber **AND**
- If member's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve tardive dyskinesia symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for the member **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amantadine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 6 mg tablet: 2 tablets per day, 30 day supply per fill
    - 9 mg tablet: 4 tablets per day, 30 day supply per fill
    - 12 mg tablet: 4 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will be for a period of one (1) year. Reevaluation of coverage will be every one (1) year and will require documentation of:

- For patients with Huntington's disease: Medical record documentation of an improvement in chorea associated with Huntington's Disease as evidenced by a reduction in the Total Maximal Chorea Score from baseline.
- For patients with Tardive Dyskinesia: Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score

If a formulary exception is approved Austedo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

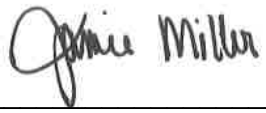
**FORMULARY ALTERNATIVES:**

Huntington's Disease: tetrabenazine*
Tardive Dyskinesia: amantadine

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/28/17 |
| Revised: | 3/1/18 – annual review, updated signature, updated age criteria & indication headers |
| Revised: | 3/1/19 – annual review, added QL approval note, removed all GPID note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 465.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ingrezza**

**cApplicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ingrezza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Ingrezza may be made for members who meet the following criteria:

**Tardive Dyskinesia**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ingrezza is prescribed by, or in consultation with, a psychiatrist or neurologist **AND**
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
    - Moderate to severe abnormal body movement (AIMS score 3 or 4) in greater than or equal to 1 body area **OR**
    - Mild abnormal body movements (AIMS score 1 or 2) in greater than or equal to 2 body areas **AND**
- Medical record documentation that the member was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the member's baseline AIMS score prior to initiating therapy **AND**
- If member's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve tardive dyskinesia symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for the member **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amantadine

**Huntington's Disease**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ingrezza is prescribed by, or in consultation with, a neurologist or psychiatrist **AND**
- Medical record documentation of a diagnosis of Huntington's Disease **AND**
- Medical record documentation of symptoms of chorea b
- Medical record documentation of patient's baseline Total Maximal Chorea Score prior to initiating therapy **AND**
- Medical record documentation of one of the following:
    - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
    - For all others: Medical record documentation of a mental health evaluation performed by the prescriber **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to tetrabenazine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day, 30 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will be for a period of one (1) year. Reevaluation of coverage will be every one (1) year and will require documentation of:

For Tardive Dyskinesia

- Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score

For Huntington's Disease

- Medical record documentation of an improvement in chorea associated with Huntington's Disease as evidenced by a reduction in the Total Maximal Chorea Score from baseline

If a formulary exception is approved Ingrezza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 465.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ingrezza |

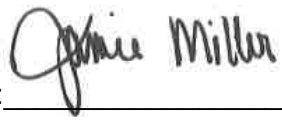
**FORMULARY ALTERNATIVES:**

Tardive Dyskinesia: amantadine
Huntington's Disease: tetrabenazine*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/28/17 |
| Revised: | 11/27/17 – updated QL to 1/day, updated signature |
| Revised: | 3/1/18 – annual review, updated age criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 2/12/24 – updated signature; added Huntington's Disease indication |
| Reviewed: | 3/1/24 |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 466.0**

**SECTION: Commercial Drug**
**SUBJECT: Tetrabenazine**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tetrabenazine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of tetrabenazine may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chorea associated with Huntington's Disease

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 12.5 mg tablet: 3 tablets per day
  - 25 mg tablet: 4 tablets per day

If a formulary exception is approved tetrabenazine will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 466.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tetrabenazine |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/28/17 |
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature |

Geisinger

**POLICY NUMBER: 467.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tymlos**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tymlos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Tymlos may be made for members who meet the following criteria:

- Medical record documentation there is no increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- Medical record documentation of a diagnosis of postmenopausal osteoporosis or osteoporosis in a male member **AND**
- Medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years* **AND**
- Medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
- Medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score –2.5 or below with documented risk factors)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1.56 mL per 30 days

**AUTHORIZATION DURATION**: Approval will be for 2 years, or less if there is medical record documentation of a previous incomplete course of therapy with a parathyroid hormone analog. Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

***NOTE:** Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

**Risk Factors Included in the WHO Fracture Risk Assessment Model**

- Current age
- Gender
- A prior osteoporotic fracture (including morphometric vertebral fracture)
- Femoral neck BMD
- Low body mass index (kg/m2)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)
- Oral glucocorticoids ≥5 mg/d of prednisone for ≥3 mo (ever)

From: WHO Technical Report.8

If a formulary exception is approved Tymlos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

alendronate, ibandronate, risedronate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/28/17

Geisinger

**POLICY NUMBER: 467.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tymlos**

| | |
|---|---|
| Revised: | 3/1/18 – annual review, updated signature |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 6/5/23 – updated signature title; added use in males |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 468.0**

**SECTION: Commercial Drug**
**SUBJECT: Siliq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Siliq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Siliq may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Siliq is prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND**
- Medical record documentation that member does not have a history of suicidal thoughts or ideations **AND**
- Medical record documentation that member does not have a history of depression **OR** medical record documentation of a concomitant diagnosis of depression and documentation that a psychiatric evaluation has been completed and member has been deemed an appropriate candidate for therapy **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of two (2) preferred formulary biologics for the treatment of psoriasis **AND**
- Medical record documentation that Siliq is <u>not</u> being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 6, min day supply 28, max day supply 28 with a duration of one month.
    - QL FOR LETTER: Loading dose: 6 mL per 28 days; Maintenance dose: 3 mL per 28 days

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of plaque psoriasis on Siliq therapy is required.

If a formulary exception is approved Siliq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

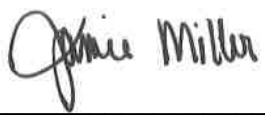
**FORMULARY ALTERNATIVES:**

Cosentyx*, Humira*, Enbrel*, Otezla*, Skyrizi*, Tremfya*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/3/17

| | |
|---|---|
| Revised: | 3/1/18 – annual review, updated signature & age criteria, added grandfather language |
| Revised: | 5/31/18 – added combination with other biologic agent, removed failure of Enbrel and added failure of Cosentyx, updated FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered |
| Revised: | 1/1/23 – updated to allow Siliq after failure of 2 preferred agents & FA for PsO, added auth duration |
| Reviewed: | 3/1/23 – annual review |
| Revised: | 3/1/24 – annual review; updated signature; updated auth entry parameters |

Geisinger

**POLICY NUMBER: 469.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Statin Quantity Limit Exception**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for statin quantity limit exceptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of statin quantity limit exceptions may be made for members who meet the following criteria:

- Medical record documentation that requested dose cannot be achieved by using a formulary alternative (i.e.- use of one 10mg tablet in place of two 5mg tablets) **AND**
- Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
- If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling **AND**
- Medical record documentation that current formulary quantity limit has been ineffective in management of member's condition

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, consider generic only depending on drug requested.

**NOTE:** Approved quantity limit exceptions should indicate the approved maximum daily dosage.

If a formulary exception is approved, the statin quantity limit exception will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 469.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Statin Quantity Limit Exception**

**FORMULARY ALTERNATIVES:**

- Atorvastatin 10 mg: 2 tablets per day
- Atorvastatin 20 mg: 1 tablet per day
- Atorvastatin 40 mg: 1 tablet per day
- Atorvastatin 80 mg: 1 tablet per day
- Fluvastatin 20 mg: 4 tablets per day
- Fluvastatin 40 mg: 2 tablets per day
- Fluvastatin ER 80 mg: 1 tablet per day
- Lovastatin 10 mg: 4 tablets per day
- Lovastatin 20 mg: 2 tablets per day
- Lovastatin 40 mg: 1 tablet per day
- Livalo 1 mg: 4 tablets per day*
- Livalo 2 mg: 2 tablets per day*
- Livalo 4 mg: 1 tablet per day*
- Pravastatin 10mg: 8 tablets per day
- Pravastatin 20 mg: 4 tablets per day
- Pravastatin 40 mg: 2 tablets per day
- Pravastatin 80 mg: 1 tablet per day
- Rosuvastatin 5 mg: 2 tablets per day
- Rosuvastatin 10 mg: 1 tablet per day
- Rosuvastatin 20 mg: 1 tablet per day
- Rosuvastatin 40 mg: 1 tablet per day
- Simvastatin 5 mg: 8 tablets per day
- Simvastatin 10 mg: 4 tablets per day
- Simvastatin 20 mg: 2 tablets per day
- Simvastatin 40 mg: 1 tablet per day
- Simvastatin 80 mg: 1 tablet per day

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/11/17
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo, updated FA
Reviewed: 3/1/23 – annual review
Revised: 3/1/24 – annual review; updated signature

Geisinger

**POLICY NUMBER: 470.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xadago**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xadago for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Xadago may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Parkinson's disease experiencing off episodes **AND**
- Medical record documentation that Xadago is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that member is concomitantly receiving carbidopa/levodopa **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member does not have severe hepatic impairment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be rasagiline or selegiline

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved Xadago will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 470.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xadago |

**FORMULARY ALTERNATIVES:**

rasagiline, entacapone, pramipexole, levodopa/carbidopa/entacapone, bromocriptine, selegiline, ropinirole, ropinirole extended release, tolcapone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/27/17 |
| Reviewed: | 3/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 471.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Haegarda**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Haegarda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Haegarda may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that Haegarda is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
    - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
    - Laryngeal edema **OR**
    - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
    - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
        - Low C4 levels **AND**
        - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
        - Less than 50% of the lower limit of normal C1-INH function levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Haegarda is being used as prophylactic therapy for hereditary angioedema (HAE) attacks

| Geisinger | POLICY NUMBER: 471.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Haegarda** |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 85802022002130 & 85802022002140)

**QUANTITY LIMIT:** 8 weight based doses per 28 days

**AUTHORIZATION DURATION**: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Haegarda will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved Haegarda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

danazol, icatibant*, Takhzyro*, Orladeyo

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: 3/1/24

Geisinger

**POLICY NUMBER: 471.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Haegarda**

| | |
|---|---|
| Devised: | 11/27/17 |
| Revised: | 3/1/18 – annual review, corrected typo |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Jamie's title |
| Revised: | 7/25/23 – removed Danazol requirement; updated FA |
| Revised: | 3/1/24 – annual review; corrected typo |

Geisinger

**POLICY NUMBER: 472.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Kevzara**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kevzara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Kevzara may be made for members who meet the following criteria:

**Rheumatoid Arthritis**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Kevzara is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (RA) made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of RA **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of rheumatoid arthritis **AND**
- Medical record documentation that Kevzara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**Polymyalgia Rheumatica**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Kevzara is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of polymyalgia rheumatica (PMR) according to American College of Rheumatology/European Union League against Rheumatism (ACR/EULAR) classification criteria **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic corticosteroids **OR**
- Medical record documentation that the member is unable to tolerate a corticosteroid taper **AND**
- Medical record documentation that Kevzara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2.28 mL per 28 days

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on Kevzara therapy is required.

If a formulary exception is approved Kevzara will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Rheumatoid Arthritis: Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*, Rinvoq*, Xeljanz*

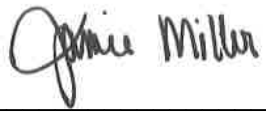
Polymyalgia Rheumatica: prednisone, methylprednisolone, prednisolone, dexamethasone, hydrocortisone

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 472.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Kevzara** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/27/17 |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 10/1/18 – removed failure of Enbrel, updated FA, added concurrent biologic crit. (RA) |
| Revised: | 3/1/19 – annual review, corrected typo, defined TNF, added QL approval note |
| Revised: | 5/3/19 – corrected typo, defined RA |
| Revised: | 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/1/23 – updated to allow Kevzara after failure of 2 preferred agents & FA for RA; added auth duration |
| Revised: | 3/1/23 – annual review; corrected typo in policy intro; updated auth parameters due to removal of PANSO; updated Jamie's title |
| Revised: | 7/25/23 – added polymyalgia rheumatica indication |
| Revised: | 3/1/24 – annual review; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 473.0**

**SECTION: Commercial Drug**
**SUBJECT: Verzenio**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verzenio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Verzenio may be made for members who meet the following criteria:

**Advanced of Metastatic Breast Cancer**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Verzenio is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-) **AND**
- One of the following:
    - Medical record documentation that Verzenio is being prescribed as initial endocrine-based therapy **AND**
    - Medical record documentation of postmenopausal status **OR** if the member is pre/perimenopausal or male, that they have received a gonadotropin-releasing hormone agonist (e.g., LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy **AND**
    - Medical record documentation that Verzenio will be prescribed in combination with an aromatase inhibitor (i.e., letrozole, anastrozole, etc.)

      **OR**

    - Medical record documentation that the patient experienced disease progression following prior endocrine therapy* **AND** prior chemotherapy^ in the metastatic setting **AND**

- Medical record documentation that Verzenio is being used as monotherapy

**OR**

- Medical record documentation that the patient experienced disease progression following prior endocrine therapy* **AND**
- Medical record documentation that fulvestrant (Faslodex) will be administered along with Verzenio **AND**
- Medical record documentation of postmenopausal status **OR** if the patient is pre/perimenopausal, that they have received a gonadotropin-releasing hormone agonist (e.g., LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy

**NOTES:**
*Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene

^Examples of preferred chemotherapy include: Anthracyclines (doxorubicin/pegylated liposomal doxorubicin), taxanes (paclitaxel), anti-metabolites (capecitabine/gemcitabine), other microtubule inhibitors (vinorelbine/eribulin). Other chemotherapy agents that can be used include: cyclophosphamide, carboplatin, docetaxel, albumin-bound paclitaxel, cisplatin, epirubicin, and ixabepilone.

**Early Breast Cancer**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Verzenio is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer **AND**
- Medical record documentation that member has a high risk of recurrence[&] **AND**
- Medical record documentation of a Ki-67 score greater than or equal to 20% determined by a Food and Drug Administration (FDA) approved test[#] **AND**
- Medical record documentation that Verzenio will be used as adjuvant treatment in combination with endocrine therapy (i.e., tamoxifen or an aromatase inhibitor) **AND**
- If patient is treated with an aromatase inhibitor (i.e., letrozole, anastrozole, etc.):
  - Medical record documentation of postmenopausal status **OR** if the patient is pre/perimenopausal or male, that they have received a gonadotropin-releasing hormone agonist (e.g., LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy

**NOTES:**
*Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene

&In clinical trials, high risk of recurrence was defined as either tumor involvement in one to three axillary lymph nodes with either tumor grade 3 disease or tumor size ≥ 50 mm **OR** tumor involvement of ≥ 4 axillary lymph nodes

#The FDA approved test for the measurement of Ki-67 score is the Ki-67 IHC MIB-1 pharmDx.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

**AUTHORIZATION DURATION:**
****For adjuvant treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node positive, early breast cancer:**
One approval will be given for 24 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Verzenio for adjuvant treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node positive, early breast cancer should not exceed the FDA-approved treatment duration of 2 year (24 months) in patients. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

**For all other indications:**
Initial approval will be for 24 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 24 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

If a formulary exception is approved Verzenio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
Ibrance*, Kisqali*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/27/17 |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 4/10/18 – added combo with aromatase inhibitor, moved requirements of postmenopausal/gonadotropin agonist therapy, updated QL |
| Revised: | Corrected typo in note, moved OR to appropriate position in last criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 1/5/22 – added males to initial endocrine-based therapy, added early breast cancer indication, updated back to Type 1 PA, added auth duration back |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Jamie's title |
| Revised: | 6/5/23 – added pre/perimenopausal to advanced BC |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 474.0**

**SECTION: Commercial Drug**
**SUBJECT: Basaglar, Semglee, and Rezvoglar**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Basaglar, Semglee, and Rezvoglar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Basaglar, Semglee, or Rezvoglar may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lantus **OR** Toujeo

**MEDISPAN AUTHORIZATION LEVEL:** NDC-9

If a formulary exception is approved Basaglar, Semglee, or Rezvoglar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

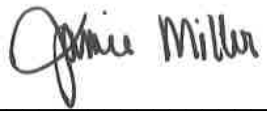
**FORMULARY ALTERNATIVES:**

Lantus, Toujeo, Tresiba, Levemir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 474.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Basaglar, Semglee, and Rezvoglar |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/27/17 |
| Reviewed: | 3/1/18 – annual review |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 4/7/23 – added Semglee |
| Revised: | 7/25/23 – added Rezvoglar |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 475.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Benlysta for Self-Administration**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Benlysta for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Benlysta for self-administration may be made for members who meet the following criteria:

**Systemic Lupus Erythematosus (SLE)**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation a diagnosis of systemic lupus erythematosus **AND**
- Medical record documentation that member has active disease **OR** recurrent flares **OR** inability to wean steroids in systemic lupus erythematosus **AND**
- Medical record documentation that Benlytsa for self-administration is prescribed by a rheumatologist **AND**
- Medical record documentation of a positive ANA/anti-dsDNA antibody **AND**
- Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g., corticosteroid, NSAID, anti-malarial or immunosuppressant) **AND**
- Medical record documentation of no central nervous system (CNS) involvement

**SLE AUTHORIZATION DURATION**: Each authorization will be for a period of 12 months. Re-review is required with medical record documentation showing a clinical benefit of one of the following:

- Improvement in functional impairment **OR**
- Decrease in the number of exacerbations since the start of Benlysta **OR**

- Decrease in the daily required dose of oral corticosteroids such as prednisone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 9942201500E520 & 9942201500D520)

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 mL per 28 days

**Lupus Nephritis (LN)**

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation that Benlytsa for self-administration is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

**LN AUTHORIZATION DURATION**: Initial approval will be for 12 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Medical record documentation of a positive clinical response to Benlysta (e.g., improvement/stabilization in UPCR, eGFR, renal-related events) **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 9942201500E520 & 9942201500D520)

**QUANTITY LIMIT:**

- **Initial Approval –** *Two authorizations must be entered.*
  - 400 mg once weekly for 4 weeks, then 200 mg once weekly thereafter
    1. In PA Hub: Add PA only with the approved authorization duration.
    2. In NCRx: Add Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 8, min day supply 28, max day supply 28, with a duration of two weeks.
       - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 4 mL per 28 days

- **Renewal –** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
  - QL FOR LETTER ONLY: 4 mL per 28 days

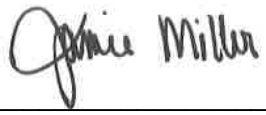
If a formulary exception is approved Benlysta for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/27/17
Revised: 12/20/17 – updated typo in prescriber bullet
Revised: 3/1/18 – annual review, corrected typo, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 01/28/20 – added criteria for age of at least 18 years
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 7/23/21 – removed nephritis from SLE indication, added LN indication, updated policy title
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered, corrected typo
Revised: 12/7/22 – updated concurrent therapy criterion for SLE to allow combo therapy or failure on

Revised: 1/9/23 – updated SLE to remove active; added active/recurrent; corrected typo; updated combo therapy, corrected typo in renewal criteria for LN
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated auth entry parameters

Geisinger

**POLICY NUMBER: 476.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Non-Preferred Acne Medications**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for non-preferred acne medications for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of non-preferred acne medications may be made for members who meet the following criteria:

- Medical record documentation a diagnosis of acne, acne vulgaris, or adult onset acne **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

If a formulary exception is approved, the non-preferred acne medication will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

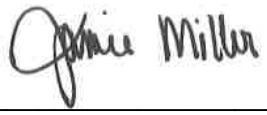
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 476.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Non-Preferred Acne Medications**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/27/17 |
| Reviewed: | 3/1/18 – annual review |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 477.0**

**SECTION: Commercial Drug**
**SUBJECT: Janumet and Janumet XR**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Janumet and Janumet XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Janumet or Janumet XR may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta in combination with metformin, Jentadueto, **OR** Jentadueto XR

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Janumet: 2 tablets per day
  - Janumet XR 50-1000 mg & 50-500 mg: 2 tablets per day
  - Janumet XR 100-1000 mg: 1 tablet per day

If a formulary exception is approved, Janumet or Janumet XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

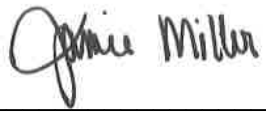
**FORMULARY ALTERNATIVES:**

metformin, Tradjenta, Jentadueto, Jentadueto XR

| Geisinger | POLICY NUMBER: 477.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Janumet and Janumet XR |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/28/17 |
| Revised: | 2/2/18 – removed new start criteria |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 480.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Calquence**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Calquence for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Calquence may be made for members who meet the following criteria:

- Medical record documentation that Calquence is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation one of the following:
    - Medical record documentation of a diagnosis of mantle cell lymphoma (MCL) **AND** therapeutic failure on, intolerance to, or contraindication to one prior therapy **OR**
    - Medical record documentation of diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- If the requested dose is 400 mg daily: Medical record documentation that the patient is using Calquence in combination with a strong CYP3A inducer, including but not limited to carbamazepine, enzalutamide, fosphenytoin, lumacaftor, mitotane, phenytoin, rifampin, St. John's Wort

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Calquence is configured as a prior authorization for new starts only. Calquence will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**NOTE:** Acalabrutinib has not been shown to be effective for ibrutinib refractory CLL/SLL in patients with BTK C481S mutations

If a formulary exception is approved Calquence will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

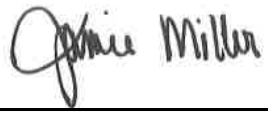
Mantle Cell Lymphoma: Imbruvica*, Brukinsa*, Revlimid*
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Imbruvica*, Venclexta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 480.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Calquence** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/18 |
| Revised: | 3/1/18 – annual review, added grandfather language, updated prescriber criteria |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 1/28/20 – added CLL/SLL indication, updated formulary alternatives |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 481.0**

**SECTION: Commercial Drug**
**SUBJECT: Nityr**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nityr for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

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5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Nityr may be made for members who meet the following criteria:

- Medical record documentation that Nityr is prescribed by a specialist in medical genetics or metabolic diseases **AND**
- Medical record documentation of a diagnosis of hereditary tyrosinemia type 1 (HT-1) established and supported by documentation of elevated plasma or urine succinylacetone (SA) levels **AND**
- Medical record documentation that Nityr will be used in combination with dietary restriction of tyrosine and phenylalanine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION**: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Nityr will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved Nityr will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 481.0**

**SECTION: Commercial Drug**
**SUBJECT: Nityr**

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/17/18
Reviewed: 3/1/18 – annual review
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 482.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nitisinone Capsules and Orfadin Suspension**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nitisinone capsules and Orfadin suspension for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of nitisinone capsules and Orfadin suspension may be made for members who meet the following criteria:

- Medical record documentation that Orfadin is prescribed by a specialist in medical genetics or metabolic diseases **AND**
- Medical record documentation of a diagnosis of hereditary tyrosinemia type 1 (HT-1) established and supported by documentation of elevated plasma or urine succinylacetone (SA) levels **AND**
- Medical record documentation that Orfadin will be used in combination with dietary restriction of tyrosine and phenylalanine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Nityr tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for nitisinone capsules include generic only.

**AUTHORIZATION DURATION**: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Nitisinone capsules or Orfadin suspension will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved nitisinone capsules or Orfadin suspension will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Nityr tablets*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/18 |
| Reviewed: | 3/1/18 – annual review |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; updated capsules to generic only |

Geisinger

**POLICY NUMBER: 484.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tremfya**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tremfya for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Tremfya may be made for members who meet the following criteria:

**Psoriasis**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tremfya is prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *Quantity limit must be entered in authorization.*

- 100 mg at weeks 0, 4, and then every 8 weeks thereafter
    1. In PA Hub: Add Treat as "Include" Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of two-weeks.
        - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 56 days

**RE-AUTHORIZATION CRITERIA:** Tremfya is configured as a prior authorization for new starts only. Tremfya will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

cyclosporine, methotrexate

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream,

ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**Psoriatic Arthritis**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tremfya is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
- For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *Quantity limit must be entered in authorization.*

- 100 mg at weeks 0, 4, and then every 8 weeks thereafter
    1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of two-weeks.
        - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 56 days

**RE-AUTHORIZATION CRITERIA:** Tremfya is configured as a prior authorization for new starts only. Tremfya will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac,

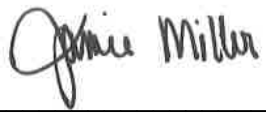
meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

If a formulary exception is approved Tremfya will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/18 |
| Revised: | 3/1/18 – annual review, added grandfather language |
| Revised: | 4/5/18 – corrected typo in approval statement |
| Revised: | 5/31/18 – added combination with other biologic agents, removed failure of Enbrel and added failure of Cosentyx, updated FA, corrected typo |
| Revised: | 3/1/19 – annual review, defined TNF |
| Revised: | 6/4/19 – updated QL, added authorization parameters |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 11/18/20 – added PsA indication, updated initial auth length to 2 weeks for PP |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered |
| Revised: | 1/1/23 – updated PsO & PsA FA to allow Tremfya as initial biologic after failure of 1st line therapy for mod/severe disease |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; updated auth entry parameters |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 487.0**

**SECTION: Commercial Drug**
**SUBJECT: Quantity Limit Exceptions**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for quantity limit exceptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A quantity limit exception may be made for members who meet the following criteria:

- Medical record documentation that requested dose cannot be achieved by using a formulary alternative (i.e.- use of one 10 mg tablet in place of two 5 mg tablets) **AND**
- Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
- If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling **AND**
- Medical record documentation that current formulary quantity limit has been ineffective in management of member's condition

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

If a quantity limit exception is approved, the drug will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

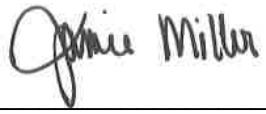
**FORMULARY ALTERNATIVES:**

not applicable

| Geisinger | POLICY NUMBER: 487.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Quantity Limit Exceptions |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/18 |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 8/21/18 – removed authorization duration |
| Revised: | 3/1/19 – annual review, defined FDA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Jamie's title |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 488.0**

**SECTION: Commercial Drug**
**SUBJECT: Opioid Use**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for opioid use for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***POS*** – point of sale
7. ***MED*** – morphine equivalent dose
8. ***OCDP*** – opioid cumulative dosing program

**POS CUMULATIVE MED EDIT PROGRAM OVERVIEW**

The program encompasses five primary components:

1. A POS-level cumulative dosing edit, which calculates cumulative opioid morphine equivalent dosing (MED) and triggers soft or hard-stop edits at time of adjudication based on MED threshold values and program inclusion and exclusion parameters
    a. Soft-stop POS Edit may be overridden by Professional Pharmacy Service (PPS) response codes or coverage determination from the Health Plan
    b. Hard-stop POS Edit may be overridden by coverage determination from the Health Plan
2. Exceptions processing to optimize edit targeting and minimize false positives, using both automated and clinical review processes as described below
3. All clinical thresholds and triggers are reviewed by the P&T committee as needed.
4. If at any point during the member review process fraudulent activity is suspected by a pharmacy, prescriber, or member they will be referred to the fraud, waste, and abuse team in accordance with Geisinger Health Plan's Universal Policy 49.

**METHODOLOGY FOR ENROLLMENT**

1. Inclusion criteria:
    a. All active, approved prescription claims meeting the following criteria will be counted for total cumulative MED for a plan beneficiary:
        i. Opioid drug has a defined dose-normalization factor in the POS system, and
        ii. Opioid is configured as program-eligible in the edit.
    b. The hard-stop MED threshold, at or above which claims will hard-stop reject, will be: 90 (50 effective 7/1/19)
    c. The minimum prescriber number threshold will be: 1

2. Exclusion criteria:
    a. Claims identified by the OCDP as overlapping refills of existing therapy will not be included in the cumulative MED calculation.
    b. History of a prior authorization override will prevent OCDP rejections as described in the Procedure section below
    c. Member is defined as a hospice member
    d. Member has active claims history of cancer medication in the last 180 days
    e. Member has a diagnosis of Sickle cell disease
3. Reject code/POS Denial Language:
    a. POS Notification: “Cumulative morphine equivalent dose of (patient’s current MED) =/exceeds threshold of (MED threshold value) per day”

**DURATION OF OPIOID USE PROGRAM OVERVIEW**
Any claim for a newly initiated (defined as no opioid claims history in the past 120 days) short-acting opioid greater than a 5 day supply for a child under the age of 18 years old or greater than a 10 day supply for an adult, or any claim for a long-acting opioid will block at point of sale and require prior authorization.

**PROCEDURE:**
Prior authorization of opioids will be made for members who meet the following criteria:

- Diagnosis of active cancer or palliative care **OR**
- Diagnosis of sickle cell disease **OR**
- Member is receiving hospice care

**NOTE:** Authorizations will be entered for an opioid class override for members who meet these criteria

**AND** For members who do not meet the above criteria:

For short-acting opioid requests to exceed an initial 5 day supply for a member under the age of 18 years or for greater than a 10 day supply for a member greater than or equal to 18 years:

- Medical record documentation of prescriber attestation that greater than a 5 day supply for members under the age or 18 or greater than a 10 day supply for members 18 years of age and older is medically necessary to treat the member’s pain **OR**
- Medical record documentation that member is already established on opioid therapy

**NOTE:** Authorizations will be entered as a one-time override, RX count 1 for the remainder of the calendar year.

**AND**

For requests exceeding the MED threshold and/or for long-acting opioids, the following documentation will be required:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line drug and non-drug treatments for pain **AND**
- Prescriber has assessed the member's pain, cause of pain, and documented the anticipated duration of therapy **AND**
- Medical record documentation that the member is:
    - being treated for non-cancer pain **AND**
        - the prescription is written by a Pain Management Specialist OR the member has been referred to a Pain Management Specialist for the same condition within the previous 24 months **OR**
        - the member has a signed pain contract in place

**AND**

- The prescriber will conduct urine drug screening (UDS), which includes testing for the prescribed opioid per the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain – United States 2016 **AND**
- Provider has evaluated member for risk of opioid use disorder using CAGE-AID, Opioid Risk Tool, or a similar screening tool upon initiation of opioids and every 3 months or as needed **AND**
- There is a plan for the tapering of benzodiazepines or rationale for continued use (if applicable) **AND**
- The prescriber has queried the State's Prescription Drug Monitoring System with every controlled substance written to ensure controlled substance history is consistent with prescribing record **AND**
- The prescriber has discussed the risks of addiction and overdose with the minor and parent, guardian or authorized adult if under the age of 18 **AND**
- If under the age of 18, the prescriber has obtained written consent for the prescription from the minor's parent/guardian/authorized adult on a standardized consent form **AND**
- There is medical record documentation that the member or parent/guardian has been educated on the potential adverse effects of opioid analgesics, including the risk for misuse, abuse and addiction **AND** the member will receive a prescription for naloxone if dose of opioid is 120 morphine equivalents (MEDs) (50 MEDs for minors) or greater and member is not being treated for end of life **OR** if the prescriber determines the member is at risk for an overdose at any MED.

**AND**

**For a long-acting opioid**:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a short-acting opioid.

**OR if the above criteria is not met:**

- The Plan will work with the prescriber and provide authorization for the requested medication during a period of tapering in accordance with accepted standards of care. During this tapering process, referral will be made to case management to offer assistance to the member during the transition process.

**AND for non-preferred opioids:**

**For non-preferred short-acting opioids:**

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred short-acting formulary alternatives, one of which must be oxycodone **OR**
- If the request is for an abuse-deterrent formulation (RoxyBond), medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

**For fentanyl citrate oral lozenge (generic Actiq)**

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation that the member has a diagnosis of cancer and is receiving scheduled opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to immediate-release morphine sulfate **OR** immediate-release oxycodone

**For Abstral, Lazanda, Fentora, Subsys**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member has a diagnosis of cancer and is receiving scheduled opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to fentanyl lozenges* (generic Actiq) **AND** immediate-release morphine sulfate **OR** immediate-release oxycodone

**For non-preferred long acting opioids:**

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine sulfate ER **OR**
- If the request is for an abuse-deterrent formulation (see table below), medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

**For Nucynta ER for neuropathic pain:**

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine sulfate ER **AND** Lyrica **AND** duloxetine

**For oxycodone ER or OxyContin:**

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine ER **OR**
- Medical record documentation that the patient is 11 to < 18 years of age **OR**
- For Oxycontin (brand) – Medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**AUTHORIZATION DURATION:**

- For chronic non-cancer pain, active cancer or palliative care, and hospice care: 1 year
- For sickle cell disease: lifetime
- For stabilization of an acute medical condition: stated duration of treatment
- For initial day supply exceeding 3 (member <18 years of age) or 5 days (members 18 years of age and older): one-time override, RX count 1 for remainder of calendar year
- For tapering the member off opioids: 1 year or the time requested by the prescriber for tapering, whichever is less

**Reference Table: Abuse-Deterrent Opioids and Routes of Abuse Each is Intended to Deter**

| | Drug Deters Abuse Via These Routes | | |
|---|---|---|---|
| **Drug** | IV/injection | Intranasal | Oral |
| Arymo ER | X | | |
| Embeda | | X | X |
| Hysingla ER | X | X | X |
| MorphaBond ER | X | X | |
| OxyContin (oxycodone ER) | X | X | |
| Troxyca ER | | X | X |
| Xtampza ER | X | X | X |
| RoxyBond | X | X | |

If an exception is made, the opioid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**NSAIDs:** celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac^, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**Short-acting opioids:** acetaminophen/codeine, butorphanol nasal spray*, codeine solution, codeine tablets, hydrocodone/acetaminophen, hydrocodone/ibuprofen, hydromorphone liquid, hydromorphone tablet, levorphanol*, meperidine, morphine solution, morphine tablet, oxycodone acetaminophen solution, oxycodone/acetaminophen tablet, oxycodone/aspirin, oxycodone/ibuprofen, oxycodone capsule, oxycodone tablet, oxycodone solution, oxymorphone, pentazocine/naloxone*, Roxicodone, tramadol, tramadol/acetaminophen

**Long-acting opioids**: buprenorphine transdermal patch*^, fentanyl transdermal patch*, methadone tablets*, morphine ER tablet*, morphine ER capsules*, oxycodone ER*, tramadol ER capsule*, tramadol ER tablet

**Additional Alternatives for Nucynta ER:** Lyrica, duloxetine

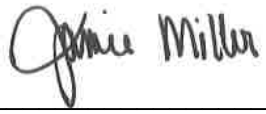
**Additional Alternatives for Abstral, Lazanda, Fentora, Subsys:** fentanyl lozenges*

* prior authorization required
^ quantity limits apply

| Geisinger | POLICY NUMBER: 488.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Opioid Use |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/15/18 |
| Reviewed: | 3/1/18 – annual review |
| Revised: | 8/20/18 – removed cough/cold from calculation, removed soft stop, updated hard stop to 90 MED, added duration of opioid use program, updated non-opioid criteria, added assessment of therapy duration criteria, added day supply criteria, updated UDS to CDC guidelines, added LA opioid criteria, added NP opioid criteria |
| Revised: | 8/28/18 – added non-preferred LA opioid/Nucynta ER for neuropathic pain/oxycodone ER criteria, added abuse deterrent reference tablet, added FA |
| Revised: | 3/1/19 – annual review, defined abbr. |
| Revised: | 6/4/19 – updated MED limit, added newly initiated to duration of use overview, added duration of use criteria for initial fills, updated description for all other criteria, removed requirement of chronic pain, removed stabilization of acute medication condition/taper |
| Revised: | 7/24/19 – added auth duration to initial day supply reviews |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/9/20 – corrected typo |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, deleted note |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 2/12/24 – updated SA opioid initial day supply limits to 5 and 10 days |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 489.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Auryxia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Auryxia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Auryxia may be made for members who meet the following criteria:

**Hyperphosphatemia**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Auryxia is prescribed by a nephrologist **AND**
- Medical record documentation of a diagnosis of chronic kidney disease (CKD) on dialysis **AND**
- Medical record documentation that Auryxia is being used to control serum phosphorus levels **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcium acetate **AND** sevelamer carbonate **AND** lanthanum carbonate

**Iron Deficiency Anemia**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Auryxia is prescribed by a nephrologist **AND**
- Medical record documentation of a diagnosis of iron deficiency anemia and chronic kidney disease **AND**
- Medical record documentation that the member is not receiving dialysis

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 12 tablets per day

If a formulary exception is approved Auryxia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

calcium acetate, sevelamer carbonate (generic Renvela), lanthanum carbonate, Fosrenol powder packet

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/5/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated Jamie's title
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY NUMBER: 490.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Cotempla XR-ODT**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cotempla XR-ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cotempla XR-ODT may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 8.6 mg and 17.3 mg tablets: 1 tablet per day
  - 25.9 mg tablets: 2 tablets per day

**NOTES:**

Per the Metadate CD prescribing information: “Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g., water, should follow

the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed."

Per the Adderall XR prescribing information: "The capsules may be taken whole or the contents of the capsule may be sprinkled on applesauce. If using the sprinkle method, the applesauce should be consumed immediately and swallowed without chewing. The dose of a single capsule should not be divided and the contents of the entire capsule should be taken."

If a formulary exception is approved Cotempla XR-ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, methylphenidate CD

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/5/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 491.0**

**SECTION: Commercial Drug**
**SUBJECT: Amphetamine/Dextroamphetamine ER Capsules (generic Mydayis)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for amphetamine/dextroamphetamine ER capsules (generic Mydayis) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of amphetamine/dextroamphetamine ER capsules (generic Mydayis) may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved amphetamine/dextroamphetamine ER capsules (generic Mydayis) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 491.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Amphetamine/Dextroamphetamine ER Capsules (generic Mydayis)** |

**FORMULARY ALTERNATIVES:**

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, methylphenidate CD

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated Jamie's title
Revised: 3/1/24 – annual review; updated to generic only

Geisinger

**POLICY NUMBER: 492.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Symproic**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symproic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Symproic may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for opioid-induced constipation associated with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment **AND**
- Medical record documentation current use of an opioid medication for greater than or equal to 4 weeks **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one stimulant laxative **AND** one osmotic laxative **AND** Movantik **AND** lubiprostone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved Symproic will be paid for under the member's prescription drug benefit.

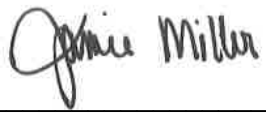
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 492.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Symproic |

**FORMULARY ALTERNATIVES:**
lubiprostone, Movantik

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Amitiza to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated Jamie's title
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 493.0**

**SECTION: Commercial Drug**
**SUBJECT: Benznidazole**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Benznidazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Benznidazole may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years and less than or equal to 12 years **AND**
- Medical record documentation that Benznidazole is prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of a diagnosis of Chagas disease confirmed by one of the following diagnostic tests:
    - Detection of circulating *Trypanosoma cruzi* trypomastigotes on microscopy **OR**
    - Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
    - Two positive diagnostic serologic tests using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 100 mg tablets: 4 tablets per day, 30 day supply per fill
    - 12.5 mg tablets: 2 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION**: 60 days, RX count 2

If a formulary exception is approved Benznidazole will be paid for under the member's prescription drug benefit.

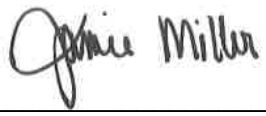
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/6/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 494.0**

**SECTION: Commercial Drug**
**SUBJECT: Baxdela Tablets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Baxdela tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Baxdela tablets may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Baxdela is prescribed by or in consultation with infectious disease **AND**
- Medical record documentation of one of the following:
    - Diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by susceptible isolates of the following: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group* (including *Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae*, or *Pseudomonas aeruginosa* **OR**
    - Diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae* **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that Baxdela therapy was started during an inpatient setting

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

**AUTHORIZATION DURATION**:

- **ABSSSI:** one-time, 14-day authorization
- **CABP:** one-time, 10-day authorization

**Note:** ABSSSI is defined as a skin infection with a lesion surface area of at least 75 $cm^2$ and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

If a formulary exception is approved Baxdela tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ciprofloxacin, clindamycin, doxycycline, levofloxacin, linezolid, minocycline, moxifloxacin, ofloxacin, sulfamethoxazole/trimethoprim

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 494.0**

**SECTION: Commercial Drug**
**SUBJECT: Baxdela Tablets**

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 4/21/20 – added CABP indication
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 495.0**

**SECTION: Commercial Drug**
**SUBJECT: Qtern**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qtern for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Qtern may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Glyxambi **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta **AND** one formulary sodium-glucose co-transporter 2 (SGLT-2) inhibitor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved Qtern will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Glyxambi, Jardiance, Synjardy, Farxiga, Xigduo XR, Tradjenta, Jentadueto

Geisinger

**POLICY NUMBER: 495.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Qtern**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/6/18 |
| Revised: | 5/3/18 – added QL as approved at 3/18 P&T |
| Revised: | 5/30/18 – updated failure to Glyxambi OR Tradjenta/SGLT2 inhibitor, updated FA |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; defined SGLT2; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 497.0**

**SECTION: Commercial Drug**
**SUBJECT: Endari**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Endari for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Endari may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation that Endari is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of a diagnosis of sickle cell disease **AND**
- Medical record documentation of Endari being used to reduce the acute complication of sickle cell disease* **AND**
- Medical record documentation intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea

***NOTE:** In clinical trials, patients were included if they had two or more painful crises within the previous 12 months.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 packets per day, 30 day supply per fill

**AUTHORIZATION DURATION**: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is required for reauthorization:

- Medical record documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e., number of sickle cell crises, hospitalizations, and number of ACS occurrences)

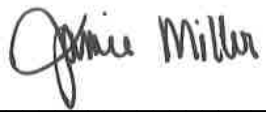
If a formulary exception is approved Endari will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
hydroxyurea

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/6/18 |
| Revised: | 5/29/18 – corrected typo in title, removed references to Tremfya |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 1/17/20 – added minimum 3 month trial on hydroxyurea, removed note on NHLBI guidelines |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Jamie's title |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 498.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Erleada**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Erleada for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Erleada may be made for members who meet the following criteria:

- Medical record documentation that Erleada is prescribed by an oncologist or urologist **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic castration-sensitive disease **OR**
  - Medical record documentation of a diagnosis of prostate cancer with evidence of non-metastatic disease **AND** member is no longer responding to castration or is hormone resistant **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Erleada is configured as a prior authorization for new starts only. Erleada will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Erleada will be paid for under the member's prescription drug benefit.

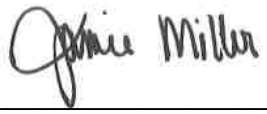
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/29/18
Revised: 6/11/18 – removed Zytiga and Xtandi from formulary alternatives
Revised: 8/21/18 – added bilateral orchiectomy to GnRH criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/20/19 – added castration-sensitive indication
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Revised: 3/1/23 – annual review; updated Jamie's title
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 499.0**

**SECTION: Commercial Drug**
**SUBJECT: Gocovri**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gocovri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Gocovri may be made for members who meet the following criteria:

**Dyskinesia with Parkinson's Disease**

- Medical record documentation of dyskinesia with a diagnosis of Parkinson's disease **AND**
- Medical record documentation that the member is currently receiving and will continue levodopa-based therapy with the addition of Gocovri **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to immediate-release amantadine

**Off Episodes with Parkinson's Disease**

- Medical record documentation of "off episodes" with a diagnosis of Parkinson's disease **AND**
- Medical record documentation that Gocovri will be used as adjunctive treatment to levodopa/carbidopa

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 68.5 mg capsule: 1 capsule per day
  - 137 mg capsule: 2 capsules per day

If a formulary exception is approved Gocovri will be paid for under the member's prescription drug benefit.

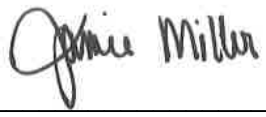
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

immediate release amantadine, benztropine, trihexyphenidyl, carbidopa/levodopa

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/29/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 7/23/21 – added off-episodes with PD indication, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated Jamie's title |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 500.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Odactra**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Odactra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Odactra may be made for members who meet the following criteria:

- Medical record documentation that Odactra is prescribed by or in consultation with an allergist, immunologist, or other physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 12 years and less than or equal to 65 years **AND**
- Medical record documentation of house dust mite-induced allergic rhinitis confirmed by *in vitro* testing for IgE antibodies to *Dematophagoides fainae* or *Dermatophagoides pteronyssinus* house dust mites **OR** skin testing to licensed house dust mite allergen extracts **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving subcutaneous immunotherapy **AND**
- Medical record documentation that Odactra will not be used in combination with sublingual immunotherapy (e.g., Grastek, Oralair, and Ragwitek) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

**AUTHORIZATION DURATION**: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The following criteria is required for reauthorization:

- Medical record documentation of sustained improvement in allergic rhinitis symptoms **AND**
- Medical record documentation that the member is tolerating Odactra

If a formulary exception is approved Odactra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/29/18

Geisinger

**POLICY NUMBER: 500.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Odactra**

Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated Jamie's title
Revised: 7/25/23 – updated aged to 12 years
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 501.0**

**SECTION: Commercial Drug**
**SUBJECT: Solosec**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Solosec for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Solosec may be made for members who meet the following criteria:

**Bacterial Vaginosis**

- Medical record documentation of a diagnosis of bacterial vaginosis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metronidazole **AND** clindamycin **AND** tinidazole

**Trichomoniasis**

- Medical record documentation of trichomoniasis caused by *Trichomonas vaginalis* **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to oral metronidazole **AND** tinidazole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 packet per 30 days

If a formulary exception is approved, Solosec will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 501.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Solosec |

**FORMULARY ALTERNATIVES:**

Bacterial vaginosis: clindamycin 2% vaginal cream, Clindesse 2% extended release vaginal cream, Cleocin 100 mg vaginal suppository, metronidazole 0.75% vaginal gel, tinidazole tablets

Trichomoniasis: oral metronidazole, tinidazole tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/30/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 1/5/22 – added trichomoniasis indication |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 6/27/22 – updated age for both indications to 12 years |
| Revised: | 3/1/23 – annual review; updated Jamie's title |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 502.0**

**SECTION: Commercial Drug**
**SUBJECT: Steglatro & Invokana**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Steglatro and Invokana for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Steglatro or Invokana may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Farxiga **AND** Jardiance

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Steglatro or Invokana will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Farxiga, Xigduo XR, Jardiance, Synjardy, Glyxambi

| Geisinger | **POLICY NUMBER: 502.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Steglatro & Invokana** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 1/1/23 – added Invokana to policy; updated preferred agents from Invokana to Farxiga
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 503.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Steglujan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Steglujan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Steglujan may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Glyxambi **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta **AND** one formulary sodium-glucose co-transporter 2 (SGLT-2) inhibitor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Steglujan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

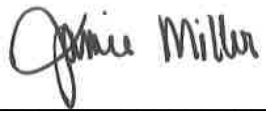
**FORMULARY ALTERNATIVES:**

Glyxambi, Jardiance, Synjardy, Farxiga, Xigduo XR, Tradjenta, Jentadueto

| Geisinger | POLICY NUMBER: 503.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Steglujan |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/30/18 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; defined SGLT2; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 504.0**

**SECTION: Commercial Drug**
**SUBJECT: Segluromet & Invokamet**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Segluromet and Invokamet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Segluromet or Invokamet may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin **OR** Synjardy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Farxiga in combination with metformin **OR** Xigduo XR

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

If a formulary exception is approved, Segluromet or Invokamet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

metformin, Jardiance, Synjardy, Farxiga, Xigduo XR, Glyxambi

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 504.0**

**SECTION: Commercial Drug**
**SUBJECT: Segluromet & Invokamet**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/30/18 |
| Revised: | 3/1/19 – annual review, added QL approval note, updated FA |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/1/23 – added Invokamet to policy; updated preferred agents to Jardiance and Farxiga |
| Revised: | 3/1/23 – annual review; corrected typo requiring failure on Invokamet; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 505.0**

**SECTION: Commercial Drug**
**SUBJECT: Prevymis**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Prevymis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Prevymis may be made for members who meet the following criteria:

**Stem Cell Transplant**

- Medical record documentation that Prevymis is prescribed by or in consultation with a hematologist/oncologist, infectious disease, and/or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that member is a confirmed cytomegalovirus (CMV) seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine)

**Kidney Transplant**

- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of cytomegalovirus (CMV) [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**

- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

**AUTHORIZATION DURATION**:

- Stem Cell Transplant: 100 days
- Kidney Transplant: 200 days

If a formulary exception is approved Prevymis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

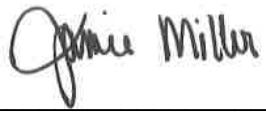
**FORMULARY ALTERNATIVES:**

valganciclovir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 505.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Prevymis** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/30/18 |
| Revised: | 8/7/18 – updated authorization duration, corrected 2 typos |
| Revised: | 3/1/19 – annual review, added QL approval note, defined CMV |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 2/12/24 – added kidney transplant indication |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 506.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Iyuzeh and Vyzulta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Iyuzeh and Vyzulta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Iyuzeh or Vyzulta may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan), tafluprost (generic Zioptan), **AND** travoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost (generic Xalatan), tafluprost (generic Zioptan), **AND** travoprost

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Iyuzeh: 30 single-dose containers (6 mL) per 30 days

If a formulary exception is approved, Iyuzeh or Vyzulta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

latanoprost (generic Xalatan), travoprost, tafluprost (generic Zioptan)*

*prior authorization required

Geisinger

**POLICY NUMBER: 506.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Iyuzeh and Vyzulta**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| | |
|---|---|
| Devised: | 5/30/18 |
| Revised: | 8/21/18 – updated to step, added failure of Zioptan, updated FA |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies, covered LOBs, & Travatan Z to travoprost |
| Revised: | 3/1/23 – annual review; updated Zioptan to tafluprost; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |
| Revised: | 4/10/24 – added Iyuzeh to policy |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 507.0**

**SECTION: Commercial Drug**
**SUBJECT: Everolimus Soluble Oral Tablet (generic Afinitor Disperz)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for everolimus soluble oral tablet (generic Afinitor Disperz) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of everolimus soluble oral tablet (generic Afinitor Disperz) may be made for members who meet the following criteria:

**Tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma**

- Medical record documentation that everolimus soluble oral tablet (generic Afinitor Disperz) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection

**Tuberous sclerosis complex (TSC)-associated partial-onset seizures**

- Medical record documentation of adjunctive treatment for adult **OR** pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) anti-epileptic drug (AED) regimens

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year, generic only

**QUANTITY LIMIT (ALL INDICATIONS):** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Everolimus soluble oral tablet (generic Afinitor Disperz) is configured as a prior authorization for new starts only. Everolimus oral soluble tablet (generic Afinitor Disperz) will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, everolimus soluble oral tablet (generic Afinitor Disperz) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Partial Onset Seizures –

Age 2 and older: carbamazepine, lamotrigine immediate release, levetiracetam immediate release, oxcarbazepine, phenobarbital, phenytoin, topiramate immediate release

Age 3 and older: carbamazepine, gabapentin, lamotrigine immediate release, levetiracetam immediate release, oxcarbazepine, phenobarbital, phenytoin, topiramate immediate release

Age 10 and older: carbamazepine, divalproex, gabapentin, lamotrigine immediate release, levetiracetam immediate release, oxcarbazepine, phenobarbital, phenytoin, topiramate immediate release

Age 12 and older: carbamazepine, divalproex, gabapentin, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

Age 13 and older: carbamazepine, divalproex, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release,

levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

Age 14 and older: carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

Age 16 and older: carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release, zonisamide

Age 18 and older: carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, Lyrica, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release, zonisamide

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated product to generic; added generic only approval language; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 508.0**

**SECTION: Commercial Drug**
**SUBJECT: Auvi-Q 0.1 mg**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Auvi-Q 0.1 mg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Auvi-Q 0.1 mg may be made for members who meet the following criteria:

- Medical record documentation of weight greater than or equal to 7.5 kilograms (16.5 pounds) and less than or equal to 15 kilograms (33 pounds)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 auto-injectors per fill

If a formulary exception is approved, Auvi-Q 0.1 mg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

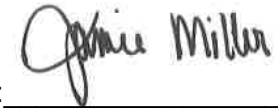
**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 508.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Auvi-Q 0.1 mg |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/30/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; defined abbreviations; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 509.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Fiasp** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fiasp for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Fiasp may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Novolog

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

If a formulary exception is approved, Fiasp will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

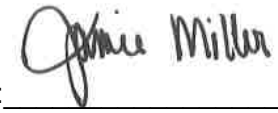
**FORMULARY ALTERNATIVES:**

Novolog, insulin aspart

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| | |
|---|---|
| Geisinger<br><br>**POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **POLICY NUMBER: 509.0**<br><br>**SECTION: Commercial Drug**<br>**SUBJECT: Fiasp** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/20/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/4/20 – removed age restriction |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 510.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Admelog**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Admelog for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Admelog may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to comparable Novo Nordisk brand insulin **OR**
- Medical record documentation that the requested insulin require dilution

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 2710400500D222 & 27104005002020)

If a formulary exception is approved, Admelog will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Novolog, insulin aspart

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

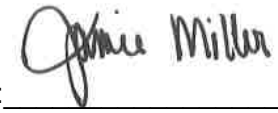
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY NUMBER: 510.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Admelog**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/20/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 511.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aimovig**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aimovig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Aimovig may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
  - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
  - Topiramate
  - Divalproex/sodium valproate
  - Amitriptyline
  - Venlafaxine **AND**
- Medical record documentation that Aimovig will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation that Aimovig will not be used in combination with botulinum toxin **OR**
- If the request is for use in combination with Botox, all of the following must be met:
  - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
  - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**AUTHORIZATION DURATION:** Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Aimovig will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- One of the following:
  - Medical record documentation that Aimovig is not being used concurrently with botulinum toxin **OR**
  - If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 mL per 28 days

| ICHD-III Diagnostic Criteria [3] | |
|---|---|
| **Migraine without Aura:** | **Migraine with Aura:** |
| A) At least five (5) attacks fulfilling criteria B through D below: | A) At least two (2) attacks fulfilling criteria B through C below: |
| B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated) | B) One (1) or more of the following fully reversible aura symptoms:<br>○ Visual<br>○ Sensory<br>○ Speech and/or language<br>○ Motor<br>○ Brainstem<br>○ Retinal |
| C) Headache with at least two (2) of the following characteristics:<br>○ unilateral location<br>○ pulsating quality<br>○ moderate to severe pain intensity | C) At least three (3) of the following:<br>○ at least one (1) aura symptom spreads over 5 or more minutes<br>○ two (2) or more aura symptoms occur in succession |

| | |
|---|---|
| ○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) | ○ each individual aura symptom lasts 5 to 60 minutes[1]<br>○ at least one (1) aura symptom is unilateral[2]<br>○ at least one (1) aura symptom is positive[3]<br>○ the aura is accompanied, or followed within 60 minutes, by a headache |
| D) At least one of the following during the headache:<br>○ nausea and/or vomiting<br>○ photophobia and phonophobia | D) Not better accounted for by another ICHD-3 diagnosis |
| E) Not better accounted for by another ICHD-3 diagnosis | |

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura

If a formulary exception is approved, Aimovig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Emgality*, Nurtec ODT*, Qulipta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 511.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aimovig**

| | |
|---|---|
| Devised: | 7/20/18 |
| Revised: | 12/28/18 – updated prescriber to include by/in consultation with headache specialist, updated QL |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – updated initial & renewal Botox criteria, added decrease in severity to renewal criteria |
| Revised: | 5/3/19 – added missing 'will not be used in combination with Botox' criteria |
| Revised: | 5/29/19 – updated QL based on new package size |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/9/20 – updated to failure of 2 alternatives |
| Revised: | 10/5/20 – added concomitant use with other preventive CGRP to initial/renewal criteria |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/20/23 – removed prescriber requirement; removed diag based on ICHD 3 criteria; removed CGRF examples from concomitant use criteria, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 4/7/23 – updated QL |
| Revised: | 3/1/24 – annual review; updated FA |

| Geisinger | POLICY NUMBER: 513.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Hemlibra** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Hemlibra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Hemlibra may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency **AND**
- Medical record documentation that Hemlibra is being used for routine prophylaxis **AND**
- Medical record documentation that Hemlibra will be for outpatient use

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Hemlibra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

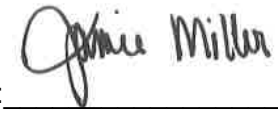
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 513.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Hemlibra** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/20/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – removed inhibitor requirement |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 514.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Antihemophilic Agents for Hemophilia A**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for antihemophilic agents for hemophilia A for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of self-administered antihemophilic agents for hemophilia A may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used appropriately for routine prophylaxis, on-demand treatment/control of bleeding episodes, **OR** perioperative management of bleeding **AND**
- If the request is for Jivi:
    - Medical record documentation of age greater than or equal to 12 years **AND**
    - Medical record documentation that the member has previously received treatment for hemophilia A with a Factor VIII product

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

| | Routine Prophylaxis | On-Demand/ Perioperative |
|---|---|---|
| Advate | X | X |
| Adynovate | X | X |
| Afstyla | X | X |
| Eloctate | X | X |
| Esperoct | X | X |
| Helixate FS | X | X |
| Hemofil M | | X |
| Jivi | X | X |
| Koate/Koate-DVI | | X |
| Kogenate FS | X | X |

| | | |
|---|---|---|
| Kovaltry | X | X |
| Novoeight | X | X |
| Nuwiq | X | X |
| Obizur | | X |
| Recombinate | | X |
| Xyntha/Xyntha Solofuse | | X |

NOTE: Obizur is indicated for adult patients with acquired hemophilia A.

If an exception is made, the antihemophilic agent for hemophilia A will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/18
Revised: 10/8/18 – removed Tretten
Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – corrected two typos, added Jivi to policy, added Obizur note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 5/29/20 – added Esperoct to policy
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated available products

Geisinger

**POLICY NUMBER: 515.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Novoseven**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Novoseven for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Novoseven may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia A or B with inhibitors, congenital Factor VII deficiency, **OR** Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used for on-demand treatment/control of bleeding episodes **OR** perioperative management of bleeding

**AND**

- For hemophilia A or B with inhibitors, medical record documentation that the member has factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (i.e. Bethesda assay)

**AND**

- For hemophilia A with inhibitors, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Feiba

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Novoseven will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 515.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Novoseven |

**FORMULARY ALTERNATIVES:**

Hemophilia A with Inhibitors: Feiba*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/20/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 516.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Feiba** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Feiba for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Feiba may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) or hemophilia B (a documented Factor IX deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the member has factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (i.e., Bethesda assay) **AND**
- Medical record documentation that the antihemophilic agent will be used for on-demand treatment or perioperative management of bleeds

**OR**

- Medical record documentation that the antihemophilic agent will be used for routine prophylaxis **AND** if being used for hemophilia A: medical record documentation of therapeutic failure on, intolerance to, or contraindication to Hemlibra

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Feiba will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 516.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Feiba |

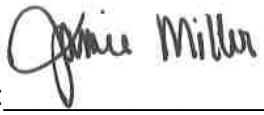
**FORMULARY ALTERNATIVES:**

Routine Prophylaxis of Hemophilia A: Hemlibra*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/20/18 |
| Revised: | 10/8/18 – added hemophilia B indication, clarified failure of Hemlibra for hemophilia A |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 517.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nocdurna**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nocdurna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nocdurna may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nocturia due to nocturnal polyuria, as defined by a night-time urine production exceeding one-third of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart **AND**
- Medical record documentation that the member is waking at least 2 times per night to void **AND**
- Medical record documentation that the member is not currently hyponatremic (serum sodium less than 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an estimated glomerular filtration rate (eGFR) greater than or equal to 50 mL/min/1.73 $m^2$ **AND**
- Medical record documentation that the member has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that Nocturna is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids

**NOTE:** the usual dosage for Nocdurna

- Females: 27.7 mcg once daily sublingually, one hour before bedtime (lower dose for women due to the higher risk of hyponatremia)
- Males: 55.3 mcg once daily sublingually, one hour before bedtime

**AUTHORIZATION DURATION:** Initial and subsequent approvals will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation that the member is experiencing clinical benefit from the use of Nocdurna **AND**
- Medical record documentation that the member is not currently hyponatremic (serum sodium less than 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an estimated glomerular filtration rate (eGFR) greater than 50 mL/min/1.73m$^2$ **AND**
- Medical record documentation that the member has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that Nocdurna is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids

**MEDISPAN AUTHORIZATION LEVEL:** Nocdurna: GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Nocdurna: 1 tablet per day

If a formulary exception is approved, Nocdurna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

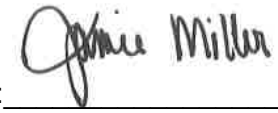
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 517.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Nocdurna** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/27/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 5/24/19 – added Nocdurna to policy
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; Noctiva D/C; updated diuretic criterion to include Nocdurna

Geisinger

**POLICY NUMBER: 518.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Symdeko**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symdeko for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Symdeko may be made for members who meet the following criteria:

- Medical record documentation that Symdeko is prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of cystic fibrosis (CF) **AND**
- Medical record documentation of one of the following, as detected by a Food and Drug Administration (FDA) cleared cystic fibrosis (CF) mutation test:
  - Medical record documentation that the member is homozygous for the *F508del* CFTR mutation **OR**
  - Medical record documentation that the member has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor per product labeling

**NOTE:** List of CFTR gene mutations that are responsive to Symdeko:

| | | | | | |
|---|---|---|---|---|---|
| *E56K* | *R117C* | *A455E* | *S977F* | *F1074L* | *3849+10kbC→T* |
| *P67L* | *E193K* | *D579G* | *F1052V* | *D1152H* | |
| *R74W* | *L206W* | *711+3A→G* | *K1060T* | *D1270N* | |
| *D110E* | *R347H* | *E831X* | *A1067T* | *2789+5G→A* | |
| *D110H* | *R352Q* | *S945L* | *R1070W* | *3272-26A→G* | |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

| Geisinger | POLICY NUMBER: 518.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Symdeko** |

**AUTHORIZATION DURATION:** Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

If a formulary exception is approved, Symdeko will be paid for under the member's prescription drug benefit.

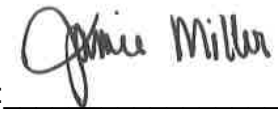
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/27/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 11/20/19 – updated age criteria to 6 years and older |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 519.0**

**SECTION: Commercial Drug**
**SUBJECT: Yonsa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Yonsa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Yonsa may be made for members who meet the following criteria:

- Medical record documentation that Yonsa is prescribed by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic disease **AND**
- Medical record documentation that the member is no longer responding to castration or is hormone resistant **AND**
- Medical record documentation that methylprednisolone will be administered concomitantly with Yonsa

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Yonsa is configured as a prior authorization for new starts only. Yonsa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Yonsa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Xtandi*, abiraterone acetate (generic Zytiga)*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 8/7/18
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 519.0**

**SECTION: Commercial Drug**
**SUBJECT: Yonsa**

Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 520.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lucemyra**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lucemyra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Lucemyra may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of use to mitigate opioid withdrawal symptoms in patients abruptly discontinuing opioids **AND**
- Medical record documentation of a Clinical Opiate Withdrawal Scale (COWS) score greater than or equal to 5 **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clonidine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 16 tablets per day, 7 day supply per fill

**AUTHORIZATION DURATION:** 14 days, number of claims authorized 2

If a formulary exception is approved, Lucemyra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 520.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lucemyra**

**FORMULARY ALTERNATIVES:**
oral clonidine, clonidine transdermal patch

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL & auth duration
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 31/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 521.0**

**SECTION: Commercial Drug**
**SUBJECT: Xhance**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xhance for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xhance may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to mometasone furoate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Xhance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

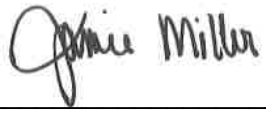
**FORMULARY ALTERNATIVES:**

mometasone furoate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 521.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Xhance** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/1/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 3/1/24 – annual review; removed failure of Beconase AQ (D/C) |

Geisinger

**POLICY NUMBER: 522.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zypitamag**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zypitamag for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions
- Policy 469.0 Statin Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zypitamag may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on (including up-to-date laboratory values), intolerance to, or contraindication to reach goal LDL (per NCEP guidelines) after titration to tolerated doses of simvastatin **AND** atorvastatin **AND** rosuvastatin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Zypitamag will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin, rosuvastatin, simvastatin, fluvastatin, lovastatin, pravastatin

Geisinger

**POLICY NUMBER: 522.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zypitamag**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; removed refence to insomnia agents; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 523.0**

**SECTION: Commercial Drug**
**SUBJECT: Rhopressa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rhopressa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Rhopressa may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be a prostaglandin analog

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.17 mL per day

**NOTE:** There are certain ocular inflammatory conditions including iritis and uveitis which do not warrant the use of Prostaglandin eye drops as first line therapy.

If a formulary exception is approved, Rhopressa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

brimonidine, latanoprost, tafluprost*, travoprost, Alphagan P, brinzolamide, Vyzulta*, Lumigan*, Simbrinza*, brimonidine/timolol*

*prior authorization or step therapy required

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 523.0**

**SECTION: Commercial Drug**
**SUBJECT: Rhopressa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/1/18 |
| Revised: | 12/28/18 – added note |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 524.0**

**SECTION: Commercial Drug**
**SUBJECT: Tavalisse**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tavalisse for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tavalisse may be made for members who meet the following criteria:

- Medical record documentation that Tavalisse is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic immune thrombocytopenia (cITP) **AND**
- Medical record documentation of symptomatic immune thrombocytopenia (ITP) with bleeding symptoms and platelet count less than 30,000/microL and bleeding symptoms **OR** a platelet count less than 30,000/microL and a documented history of significant bleeding **OR** a platelet count of less than 20,000/microL **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) of the following:
    - Corticosteroids
    - Intravenous Immunoglobulin (IVIG)*
    - Rhogam (if RhD-positive and spleen intact)
    - Rituximab*
    - Splenectomy
    - Promacta*/Nplate*/Doptelet*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

| Geisinger | POLICY NUMBER: 524.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tavalisse |

**AUTHORIZATION DURATION:** Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months. Continued coverage will require:

- Medical record documentation of platelet count greater than or equal to 50,000/microL and continued or sustained reduction in bleeding events.

If a formulary exception is approved, Tavalisse will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

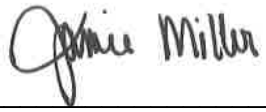
**FORMULARY ALTERNATIVES:**

prednisone, dexamethasone, Promacta*, Doptelet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/1/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 6/7/22 – upd. platelet count criterion, corrected typos, upd. Rituxan to rituximab, added Doptelet |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 525.0**

**SECTION: Commercial Drug**
**SUBJECT: Braftovi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Braftovi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Braftovi may be made for members who meet the following criteria:

**Melanoma**

- Medical record documentation that Braftovi is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of a BRAF V600E or V600K mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Braftovi is being prescribed in combination with Mektovi*

**NOTE:** Braftovi may be temporarily used as monotherapy if Mektovi must be held for any reason. If Mektovi is to be discontinued permanently, Braftovi should also be discontinued.

**Colorectal Cancer**

- Medical record documentation that Braftovi is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**

- Medical record documentation of a BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that member has had progression on at least one prior therapy **AND**
- Medical record documentation that Braftovi is being prescribed in combination with cetuximab

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- Melanoma - *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
  - In PA Hub: Add PA, max number of claims authorized 1, enter for the remainder of the calendar year.
    - QL FOR LETTER ONLY: 6 tablets per day, 30 day supply per fill
- Colorectal Cancer – *QL must be entered within the authorization*
  - In PA Hub: Add PA, max number of claims authorized 1, enter for the remainder of the calendar year.
  - In NCRx: Add Ignore Misc Handler, and max daily dose 4, min/max day supply 30.
    - QL FOR LETTER: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Braftovi is configured as a prior authorization for new starts only. Braftovi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Braftovi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Melanoma: Tafinlar*, Zelboraf*

*prior authorization required

| Geisinger | POLICY NUMBER: 525.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Braftovi |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/1/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/4/20 – added colorectal cancer indication |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed 50 mg QL due to D/C |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how auth is entered |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; updated auth entry parameters |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 526.0**

**SECTION: Commercial Drug**
**SUBJECT: Mektovi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mektovi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Mektovi may be made for members who meet the following criteria:

- Medical record documentation that Mektovi is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of a BRAF V600E or V600K mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Mektovi is being prescribed in combination with Braftovi

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Mektovi is configured as a prior authorization for new starts only. Mektovi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Mektovi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

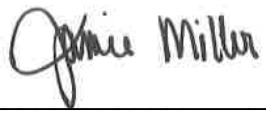
**FORMULARY ALTERNATIVES:**

Mekinist*, Cotellic*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 527.0**

**SECTION: Commercial Drug**
**SUBJECT: Jynarque**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jynarque for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Jynarque may be made for members who meet the following criteria:

- Medical record documentation that Jynarque is prescribed by a nephrologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) as confirmed by cysts and family history or genetic testing **AND**
- Medical record documentation of an estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min **AND**
- Medical record documentation the member is at risk for rapidly progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD) as documented by one of the following:
    - Mayo classification class 1C, 1D, or 1E
    - Total Kidney Volume greater than 750 mL
    - PROPKD score greater than 6
    - Kidney length greater than 16.5 cm as measured by ultrasound (if CT and MRI contraindicated)

**NOTE:** Per nephrology at Geisinger, the diagnosis of ADPKD should be established through genetic testing or modified Pei-Ravine criteria:

- With family history: several cysts per kidney (3 if by sonography; 5 if by CT or MRI)
- Without family history: 10 cysts per kidney (by any radiologic method, above) and exclusion of other cystic kidney diseases

**MEDISPAN AUTHORIZATION LEVEL:** Must enter GPI-12 3045406000B7, NDC-9 591480082, NDC-9 591480083

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to end-stage renal disease (ESRD).

If a formulary exception is approved, Jynarque will be paid for under the member's prescription drug benefit.

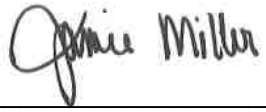
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/1/18
Revised: 12/28/18 – added diagnosis confirmation, eGFR, definition of high risk, note
Revised: 3/1/19 – annual review, added QL approval note, defined abbr.
Revised: 5/3/19 – removed asterisk following genetic testing criteria
Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 528.0**

**SECTION: Commercial Drug**
**SUBJECT: Tibsovo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tibsovo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tibsovo may be made for members who meet the following criteria:

**Newly Diagnosed AML**

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of newly diagnosed acute myeloid leukemia **AND**
- Medical record documentation that Tibsovo will be used as monotherapy or in combination with azacitidine **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of age greater than or equal to 75 years **OR**
    - Medical record documentation of age greater than or equal to 18 years **AND** comorbidities† that preclude the use of intensive induction chemotherapy

**Relapsed or Refractory AML**

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia **AND**

- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test

**NOTE:** †In the clinical trials, comorbidities that precluded the use of intensive induction chemotherapy included at least one of the following criteria: baseline ECOG performance status of ≥ 2, severe cardiac or pulmonary disease, hepatic impairment with bilirubin > 1.5 X ULN, or creatinine clearance < 45 mL/min. The FDA approved test for IDH1 is the Abbott RealTime IDH1 Assay.

**Locally Advanced or Metastatic Cholangiocarcinoma**

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that member has been previously treated with at least one prior therapy

**Relapsed or Refractory Myelodysplastic Syndrome (MDS)**

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or myelodysplastic syndromes (MDS) **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Tibsovo is configured as a prior authorization for new starts only. Tibsovo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tibsovo will be paid for under the member's prescription drug benefit.

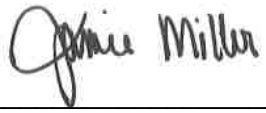
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/1/18
Revised: 11/26/18 – removed Mektovi typo
Revised: 3/1/19 – annual review, added QL approval note
Revised: Added newly diagnosed AML, added headers
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added cholangiocarcinoma indication, added one-time PA language to approval criteria, removed auth duration & added re-auth criteria
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 6/27/22 – added criterion for monotherapy or with azacitidine for newly diagnosed AML

Revised: 3/1/23 – annual review; updated signature title
Revised: 2/12/24 – added MDS indication
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 529.0**

**SECTION: Commercial Drug**
**SUBJECT: Pregabalin ER**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pregabalin ER for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of pregabalin ER may be made for members who meet the following criteria:

**Diabetic Peripheral Neuropathy**

- Medical record documentation of neuropathic pain associated with diabetic peripheral neuropathy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to duloxetine **AND** pregabalin

**Postherpetic Neuralgia**

- Medical record documentation of postherpetic neuralgia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to gabapentin **AND** pregabalin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 82.5 and 165 mg tablets: 3 tablets per day
  - 330 mg tablets: 2 tablets per day

If a formulary exception is approved, pregabalin ER will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 529.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Pregabalin ER |

**FORMULARY ALTERNATIVES:**

Diabetic Peripheral Neuropathy: duloxetine, pregabalin
Postherpetic Neuralgia: gabapentin, pregabalin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/26/18 |
| Revised: | 3/1/19 – annual review, updated QL approval note |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies, covered LOBs, & Lyrica/Lyrica CR to generic |
| Revised: | 3/1/23 – annual review; added generic only approval language; updated signature title |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 530.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Olumiant** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Olumiant for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***DMARD*** – disease modifying anti-rheumatic drug

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of rheumatoid arthritis**
An exception for coverage of Olumiant may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Olumiant is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of rheumatoid arthritis **AND**
- Medical record documentation that Olumiant is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on Olumiant therapy is required.

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Rinvoq*, Xeljanz/XR*, Enbrel*

*prior authorization required

**For treatment of severe alopecia areata**
An exception for coverage of Olumiant may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of severe alopecia areata, defined as at least 50% scalp hair lose as measured by the Severity of Alopecia Tool (SALT) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one of the following:
    - Systemic therapy used for at least 3 months (for example, corticosteroids, methotrexate, cyclosporine) **OR**
    - Prescription topical corticosteroids used for at least 28 days **OR**
    - Intralesional corticosteroids used for at least 3 months **AND**
- Medical record documentation that member does not have hair loss due to androgenetic alopecia (includes male and female pattern hair loss), chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata **AND**
- Medical record documentation that Olumiant is not prescribed in combination with other Janus kinase inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of alopecia areata on Olumiant therapy is required.

**FORMULARY ALTERNATIVES:**
prednisone, methylprednisolone, dexamethasone, prednisolone
**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate

0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam (Temovate/Clobex/Olux); diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E); fluocinonide 0.1% cream (Vanos); halobetasol 0.05% cream and ointment (Ultravate)

| Geisinger | POLICY NUMBER: 530.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Olumiant |

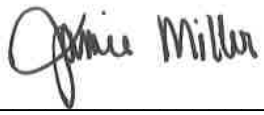
**For treatment of COVID-19**
If Olumiant is being prescribed for COVID-19, see the FDA website for the Olumiant Prescribing Information and Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA approved and EUA authorized use. At this time, Olumiant is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

If an exception is made, Olumiant will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added COVID note
Revised: 10/6/22 – updated note to reviewer related to COVID
Revised: 1/1/23 – updated to allow Olumiant after failure of 2 preferred agents & FA, added auth duration
Revised: 3/1/23 – annual review; removed PANSO approval language; updated signature
Revised: 2/12/24 – added alopecia areata indication
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 531.0**

**SECTION: Commercial Drug**
**SUBJECT: Copiktra**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Copiktra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Copiktra may be made for members who meet the following criteria:

- Medical record documentation that Copiktra is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of either:
  - Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **OR**
  - Relapsed or refractory follicular lymphoma (FL)
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) prior therapies

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Copiktra is configured as a prior authorization for new starts only. Copiktra will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Copiktra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

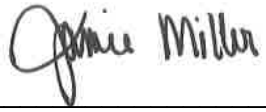
**FORMULARY ALTERNATIVES:**

CLL/SLL: Imbruvica*, Venclexta*, Zydelig*
FL: Zydelig*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 532.0**

**SECTION: Commercial Drug**
**SUBJECT: Ajovy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ajovy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ajovy may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
  - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
  - Topiramate
  - Divalproex/sodium valproate
  - Amitriptyline
  - Venlafaxine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: Aimovig, Emgality, Nurtec ODT, and Qulipta **AND**
- Medical record documentation that Ajovy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation that Ajovy will not be used in combination with botulinum toxin **OR**
- If the request is for use in combination with Botox, all of the following must be met:
  - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
  - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**AUTHORIZATION DURATION:** Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Ajovy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- One of the following:
  - Medical record documentation that Ajovy is not being used concurrently with botulinum toxin **OR**
  - If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4.5 mL per 84 days

| **ICHD-III Diagnostic Criteria** [3] | |
|---|---|
| **Migraine without Aura:** | **Migraine with Aura:** |
| A) At least five (5) attacks fulfilling criteria B through D below: | A) At least two (2) attacks fulfilling criteria B through C below: |
| B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated) | B) One (1) or more of the following fully reversible aura symptoms:<br>○ Visual<br>○ Sensory<br>○ Speech and/or language<br>○ Motor<br>○ Brainstem<br>○ Retinal |
| C) Headache with at least two (2) of the following characteristics:<br>○ unilateral location<br>○ pulsating quality<br>○ moderate to severe pain intensity | C) At least three (3) of the following:<br>○ at least one (1) aura symptom spreads over 5 or more minutes<br>○ two (2) or more aura symptoms occur in succession |

| | |
|---|---|
| ○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) | ○ each individual aura symptom lasts 5 to 60 minutes[1]<br>○ at least one (1) aura symptom is unilateral[2]<br>○ at least one (1) aura symptom is positive[3]<br>○ the aura is accompanied, or followed within 60 minutes, by a headache |
| D) At least one of the following during the headache:<br>○ nausea and/or vomiting<br>○ photophobia and phonophobia | D) Not better accounted for by another ICHD-3 diagnosis |
| E) Not better accounted for by another ICHD-3 diagnosis | |

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura

If a formulary exception is approved, Ajovy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

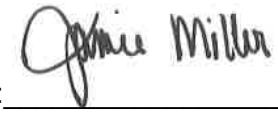
metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Aimovig*, Emgality*, Nurtec ODT*, Qulipta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 532.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Ajovy** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/26/18 |
| Revised: | 3/1/19 – annual review, added QL approval note |
| Revised: | 3/28/19 – updated initial & renewal Botox criteria, added decrease in severity to renewal criteria |
| Revised: | 5/3/19 – added missing 'will not be used in combination with Botox' criteria |
| Revised: | 7/23/19 – corrected Aimovig typo |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/9/20 – added failure of Aimovig & Emgality |
| Revised: | 10/5/20 – added concomitant use with other preventive CGRP to initial/renewal crit., updated FA |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/20/23 – updated to failure of 2 generic alts; updated to failure of 2 preferred CGRP's; removed prescriber requirement; removed diag based on ICHD 3 criteria; removed CGRF examples from concomitant use criteria, updated FA |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 4/7/23 – updated QL |
| Revised: | 11/1/23 – added Qulipta to preferred CGRP alternatives |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 533.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Emgality**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Emgality for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Emgality may be made for members who meet the following criteria:

**Migraine**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
    - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/sodium valproate
    - Amitriptyline
    - Venlafaxine **AND**
- Medical record documentation that Emgality will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation that Emgality will not be used in combination with botulinum toxin **OR**
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**AUTHORIZATION DURATION:** Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Emgality will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- One of the following:
    - Medical record documentation that Emgality is not being used concurrently with botulinum toxin **OR**
    - If the request is for use in combination with Botox, all of the following must be met:
        - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
        - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14 (must enter 6770203530D520 & 6770203530E520)

**QUANTITY LIMIT:**

- **Initial Approval –** *Two authorizations must be entered.*
    - 240 mg once, then 120 mg once monthly
        1. In PA Hub: Add PA only.
        2. In Darwin: Add OQL, DS, max number of claims authorized 1, max quantity dispensed 2, min day supply 30, max day supply 30, with a duration of two weeks.
            - QL FOR LETTER: Loading dose: 2 mL per 30 days; Maintenance dose: 1 mL per 28 days
- **Renewal**
    - 120 mg once monthly – *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
        - QL FOR LETTER: 1 mL per 28 days

**ICHD-III Diagnostic Criteria**

| Migraine without Aura: | Migraine with Aura: |
|---|---|
| A) At least five (5) attacks fulfilling criteria B through D below: | A) At least two (2) attacks fulfilling criteria B through C below: |
| B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated) | B) One (1) or more of the following fully reversible aura symptoms:<br>o Visual<br>o Sensory<br>o Speech and/or language<br>o Motor<br>o Brainstem<br>o Retinal |
| C) Headache with at least two (2) of the following characteristics:<br>o unilateral location<br>o pulsating quality<br>o moderate to severe pain intensity<br>o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) | C) At least three (3) of the following:<br>o at least one (1) aura symptom spreads over 5 or more minutes<br>o two (2) or more aura symptoms occur in succession<br>o each individual aura symptom lasts 5 to 60 minutes[1]<br>o at least one (1) aura symptom is unilateral[2]<br>o at least one (1) aura symptom is positive[3]<br>o the aura is accompanied, or followed within 60 minutes, by a headache |
| D) At least one of the following during the headache:<br>o nausea and/or vomiting<br>o photophobia and phonophobia | D) Not better accounted for by another ICHD-3 diagnosis |
| E) Not better accounted for by another ICHD-3 diagnosis | |

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura

**Episodic Cluster Headache**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of baseline cluster headache attack frequency (e.g. weekly headache attack frequency) **AND**
- Medical record documentation the member is currently experiencing a cluster headache period (period of recurrent attacks) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to suboccipital steroid injections **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to verapamil

**AUTHORIZATION DURATION:** Initial approval will be for six (6) months and subsequent approvals will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation the member is currently experiencing a cluster headache period (period of recurrent attacks) **AND**
- Medical record documentation of continued or sustained reduction in cluster headache attack frequency

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 mL per 28 days

| ICHD-III Diagnostic Criteria | |
|---|---|
| **Diagnosis of Cluster Headache** | **Diagnosis of Episodic Cluster Headache** |
| At least 5 attacks fulfilling the following criteria: | Diagnosis of Cluster Headache fulfilling occurring in bouts (cluster periods) the following criteria: |
| • Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated)<br>*During part (but less than half) of the active time-course attacks may be less severe and/or of shorter or longer duration.* | At least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥ 3 months. |
| **One or both of the following:**<br>• At least one of the following symptoms or signs, ipsilateral to the headache:<br>o Conjunctival injection and/or lacrimation<br>o Nasal congestion and/or rhinorrhea<br>o Eyelid edema<br>o Forehead and facial sweating<br>o Miosis and/or ptosis<br>• A sense of restlessness or agitation | |
| Occurring with a frequency between one every other day and 8 per day<br>*During part (but less than half) of the active time-course attacks may be less frequent* | |
| Not better accounted for by another ICHD-3 another ICHD-3 diagnosis | |

If a formulary exception is approved, Emgality will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Migraine: metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Aimovig*, Nurtec ODT*, Qulipta*

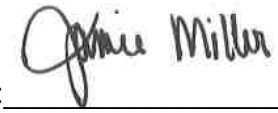
Episodic Cluster Headache: verapamil

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 533.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Emgality** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/26/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/28/19 – updated initial & renewal Botox criteria, added decrease in severity to renewal criteria |
| Revised: | 5/3/19 – added missing 'will not be used in combination with Botox criteria |
| Revised: | 6/4/19 – corrected Aimovig typo, added authorization parameters |
| Revised: | 7/23/19 – added cluster headache indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 6/9/20 – updated to failure of 2 alternatives for migraine |
| Revised: | 10/5/20 – added concomitant use with other preventive CGRP to initial/renewal criteria |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered |
| Revised: | 1/20/23 – for migraine: removed prescriber requirement; removed diag based on ICHD 3 criteria; removed CGRF examples from concomitant use criteria, updated FA |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 4/7/23 – updated QL, removed prescriber requirements from episodic cluster headaches |
| Revised: | 3/1/24 – annual review; updated FA |

Geisinger

**POLICY NUMBER: 534.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Palynziq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Palynziq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Palynziq may be made for members who meet the following criteria:

- Medical record documentation that Palynziq is prescribed by a metabolic specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of phenylketonuria (PKU) **AND**
- Medical record documentation of phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management (e.g., dietary restriction of Phe and protein intake, use of medical foods, and/or Kuvan) **AND**
- Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kuvan **AND**
- Medical record documentation that Palynziq will not be used in combination with Kuvan

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 2.5mg/0.5 mL syringe: 4 mL per 28 days
  - 10 mg/0.5 mL syringe: 14 mL per 28 days
  - 20 mg/mL syringe: 84 mL per 28 days

**AUTHORIZATION DURATION:** Initial and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a 20% reduction in phenylalanine concentration from baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L **OR**
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in phenylalanine tolerance

If a formulary exception is approved, Palynziq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Kuvan*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/26/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/26/21 – updated QL for 20 mg syringe to 84 mL per 28 days
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; corrected typo; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 535.0**

**SECTION: Commercial Drug**
**SUBJECT: Orilissa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orilissa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Orilissa may be made for members who meet the following criteria:

- Medical record documentation that Orilissa is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe pain associated with endometriosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one formulary extended-cycle contraceptive **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary nonsteroidal anti-inflammatory drugs (NSAIDs)

**NOTE:** Available extended-cycle contraceptives include: Amethia, Amethyst, Ashlyna, Camrese, Camrese Lo, Daysee, Dolishale, Jaimiess, Jolessa, Joyeaux, levonorgestrel-ethinyl estradiol, LoJaimiess, Quartette, Rivelsa, Setlakin, Simpesse, Medroxyprogesterone Acetate, and the intrauterine devices: Mirena, Liletta, Kyleena, Skyla, and ParaGard.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 150 mg tablet: 30 tablets per 30 days
  - 200 mg tablet: 60 tablets per 30 days

**AUTHORIZATION DURATION:**

- **Orilissa 150mg tablets**: Initial approval will be for 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with Orilissa 150 mg tablets).
- **Orilissa 200mg tablets:** Initial approval will be for 6 months (or less if there is medical record documentation of a previous incomplete course of therapy with Orilissa 200 mg tablets).

**REAUTHORIZATION:** Medical record documentation that the patient has not been treated for more than a total of 24 months with Orilissa 150 mg once daily OR more than a total of 6 months with Orilissa 200 mg twice daily OR documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration.

If a formulary exception is approved, Orilissa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

NSAIDs: celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac**, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

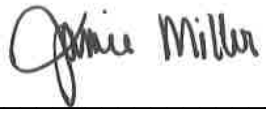
Available extended-cycle contraceptives include: Amethia, Amethyst, Ashlyna, Camrese, Camrese Lo, Daysee, Dolishale, Jaimiess, Jolessa, Joyeaux, levonorgestrel-ethinyl estradiol, LoJaimiess, Quartette, Rivelsa, Setlakin, Simpesse, Medroxyprogesterone Acetate, and the intrauterine devices: Mirena, Liletta, Kyleena, Skyla, and ParaGard.

**quantity limit applies

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 535.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Orilissa** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/26/18 |
| Revised: | 3/1/19 – annual review, defined NSAIDs |
| Revised: | 3/28/19 – removed 200 mg requirement |
| Revised: | 7/12/19 – updated and defined ketorolac QL indicator |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 6/7/21 – updated authorization duration criteria, updated GPI level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo |
| Revised: | 3/1/23 – annual review; updated note & FA with available extended cycle contraceptives; updated signature |
| Revised: | 3/1/24 – annual review; updated available extended cycle contraceptives |

Geisinger

**POLICY NUMBER: 536.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Doptelet**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Doptelet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Doptelet may be made for members who meet the following criteria:

**<u>Thrombocytopenia in Members with Chronic Liver Disease Undergoing Procedure</u>**

- Medical record documentation that Doptelet is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist, or endocrinologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of thrombocytopenia in adult patients with chronic liver disease **AND**
- Medical record documentation of a platelet count of less than 50 x $10^9$/L measured within the past 30 days **AND**
- Medical record documentation of a planned invasive procedure to be performed 10-13 days after initiation date for Doptelet treatment **AND**
- Medical record documentation that the member is not receiving other thrombopoietin receptor agonists (TPO-Ras) (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of the correct dose being used (Platelet count 40,000 to less than 50,000 x $10^9$/L - 40 mg once daily for 5 consecutive days **OR** for platelet count less than 40,000 x $10^9$/L - 60 mg once daily for 5 consecutive days)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Platelet count 40,000 to less than 50,000 x $10^9$/L: 10 tablets per fill
  - Platelet count less than 40,000 x $10^9$/L: 15 tablets per fill

**AUTHORIZATION DURATION:** 30 days, RX count 1

**Chronic Immune Thrombocytopenia**

- Medical record documentation that Doptelet is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic immune thrombocytopenia (cITP) **AND**
- Medical record documentation of symptomatic ITP with bleeding symptoms and platelet count of less than 30 x $10^9$/L **OR** a documented history of significant bleeding and platelet count less than 30 x $10^9$/L **OR** platelet count of less than 20 x $10^9$/L **AND**
- Medical record documentation that the member is not receiving other thrombopoietin receptor agonists (TPO-Ras) (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) previous treatments, including, but not limited to:
    - Corticosteroids
    - IVIG*
    - Rhogam (if RhD-positive and spleen intact)
    - Rituximab*
    - Splenectomy
    - Promacta*/Nplate*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months.

Reauthorization criteria:

- Medical record documentation of platelet count greater than or equal to 50x $10^9$/L and continued or sustained reduction in bleeding events **AND**
- One of the following:
    - Medical record documentation that the platelet count does not exceed 400 x $10^9$/L **OR**
    - If the platelet count does exceed 400 x $10^9$/L, medical record documentation that the dose will be adjusted AND documentation that the member has not been on 20 mg once weekly for 2 weeks

If a formulary exception is approved, Doptelet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

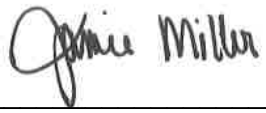
Chronic Liver Disease: Promacta*, Mulpleta*

cITP: Promacta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/27/18 |
| Revised: | 2/5/19 – added failure of Mulpleta, updated FA |
| Revised: | 3/1/19 – annual review, defined TPO-Ras |
| Revised: | 3/21/19 – added interventional radiologist to prescriber criteria |
| Revised: | 11/20/19 – removed failure of Mulpleta for liver disease, added cITP indication |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 6/7/22 – added history of bleeding and platelets < 30, removed increased risk of bleeding for platelets < 20, corrected typo in cITP |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 537.0**

**SECTION: Commercial Drug**
**SUBJECT: Vizimpro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vizimpro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vizimpro may be made for members who meet the following criteria:

- Medical record documentation that Vizimpro is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion of exon 21 L858R substitution mutations as detected by a Food and Drug Administration (FDA)-approved test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Vizimpro is configured as a prior authorization for new starts only. Vizimpro will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Vizimpro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

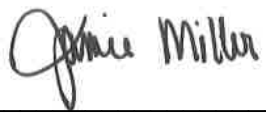
**FORMULARY ALTERNATIVES:**

Gilotrif*, gefitinib*, Tagrisso*, erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/28/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 538.0**

**SECTION: Commercial Drug**
**SUBJECT: Epidiolex**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epidiolex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Epidiolex may be made for members who meet the following criteria:

- Medical record documentation that Epidiolex is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of either Lennox-Gastaut syndrome or Dravet syndrome **AND**
- **For Lennox-Gastaut syndrome:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) generic formulary alternatives **OR** member age between 1 and 2 years

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Epidiolex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 538.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Epidiolex |

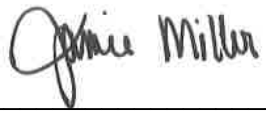
**FORMULARY ALTERNATIVES:**

For patients > 2 years of age: clonazepam, felbamate, lamotrigine, topiramate, topiramate ER*, rufinamide*, clobazam

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 12/27/18 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 10/12/20 – updated age to 1 year, added age criteria for Lennox Gastaut alternative criteria |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 539.0**

**SECTION: Commercial Drug**
**SUBJECT: Lorbrena**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lorbrena for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lorbrena may be made for members who meet the following criteria:

- Medical record documentation that Lorbrena is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 25 mg tablet: 3 tablets per day, 30 day supply per fill
  - 100 mg tablet: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Lorbrena is configured as a prior authorization for new starts only. Lorbrena will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Lorbrena will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

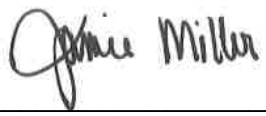
**FORMULARY ALTERNATIVES:**

Xalkori*, Zykadia*, Alecensa*, Alunbrig*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/5/19
Revised: 3/1/19 – annual review, defined ALK
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 6/7/21 – removed failure of prior agents
Revised: 11/29/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 540.0**

**SECTION: Commercial Drug**
**SUBJECT: Lokelma**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lokelma for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Lokelma may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hyperkalemia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that attempt has been made to identify and correct the underlying cause of the patient's hyperkalemia **OR** rationale as to why the underlying cause cannot be corrected **AND**
- For mild hyperkalemia (serum potassium greater than or equal to 5.1 mEq/L and less than 5.5 mEq/L): Medical record documentation that a low potassium diet has been tried and was unsuccessful at controlling the patient's serum potassium level **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to loop diuretic or thiazide diuretic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 5 g packet: 1 packet per day
  - 10 g packet: 1.14 packets per day

If a formulary exception is approved Lokelma will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 540.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Lokelma |

**FORMULARY ALTERNATIVES:**
sodium polystyrene sulfonate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/5/19
Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – removed mild/moderate & lab requirement
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature title
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 541.0**

**SECTION: Commercial Drug**
**SUBJECT: Mulpleta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mulpleta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Mulpleta may be made for members who meet the following criteria:

- Medical record documentation that Mulpleta is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist, or endocrinologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of thrombocytopenia in adult patients with chronic liver disease **AND**
- Medical record documentation of a platelet count of less than 50 x $10^9$/L measured within the past 30 days **AND**
- Medical record documentation of a planned invasive procedure to be performed 8-14 days after initiation date for Mulpleta treatment **AND**
- Medical record documentation that the member is not receiving other thrombopoietin receptor agonists (TPO-Ras) (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of the correct dose being used (3 mg orally once daily for 7 days) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Doptelet

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 7 tablets per fill

**AUTHORIZATION DURATION:** 30 days, RX count 1

If a formulary exception is approved, Mulpleta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

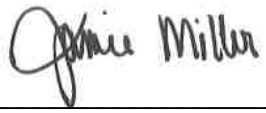
**FORMULARY ALTERNATIVES:**

Promacta*, Doptelet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/5/19 |
| Revised: | 3/1/19 – annual review, defined TPO-Ras |
| Revised: | 3/21/19 – added interventional radiologist to prescriber criteria |
| Revised: | 11/20/19 – added failure of Doptelet |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 542.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Galafold**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Galafold for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Galafold may be made for members who meet the following criteria:

- Medical record documentation that Galafold is prescribed by or in consultation with a geneticist, nephrologist, cardiologist, or a physician who specializes in the treatment of Fabry disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Fabry disease as confirmed by one of the following:
    - Enzyme assay indicating deficiency of Alpha Gal-a (if male) **OR**
    - Genetic test documenting galactosidase alpha gene mutation **AND**
- Medical record documentation of in vitro assay data confirming the presence of an amenable galactosidase alpha gene (GLA) variant, in accordance with the Food and Drug administration (FDA)-approved prescribing information **AND**
- Medical record documentation that Galafold will not be used concurrently with enzyme replacement therapy intended for the treatment of Fabry disease, such as agalsidase beta (Fabrazyme)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 14 capsules per 28 days

**AUTHORIZATION DURATION: Initial approval** will be for a duration of **six** (**6) months.** For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Fabry disease on six (6) months of migalastat is required. After the initial six (6) month approval, **subsequent approvals** for coverage will be for a duration of **one (1) year.** Reevaluation of coverage will be every one (1) year requiring medical record documentation of clinical improvement or lack of progression in signs and symptoms of Fabry disease while on migalastat therapy.

Note: Examples of disease improvement may include:

- Decreased symptoms of Fabry disease (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
- Imaging (brain/cardiac MRI, DEXA, renal ultrasound)
- Laboratory testing (e.g., GL-3 in plasma/urine) or histological tests (e.g., renal biopsy)

If a formulary exception is approved, Galafold will be paid for under the member's prescription drug benefit.

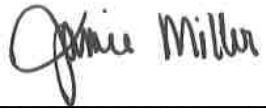
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Geisinger

**POLICY NUMBER: 542.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Galafold**

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/5/19 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; removed reference to Lorbrena |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 543.0**

**SECTION: Commercial Drug**
**SUBJECT: Takhzyro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Takhzyro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Takhzyro may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Takhzyro is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
    - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
    - Laryngeal edema **OR**
    - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
    - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
        - Low C4 levels **AND**
        - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
        - Less than 50% of the lower limit of normal C1-INH functions levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Takhzyro is being used as prophylactic therapy for hereditary angioedema (HAE) attacks **AND**

- Medical record documentation that member is receiving an appropriate dose* based on age

***NOTE:**

- **Adult and Pediatric Patients 12 Years of Age and Older:** 300 mg subcutaneously (SQ) every 2 weeks. [A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months].
- **Pediatric Patients 2 to Less Than 12 Years of Age**:
  - Pediatric Patients 6 to Less Than 12 Years of Age: Starting dosage: 150 mg SQ every 2 weeks. [A dosing interval of 150 mg every 4 weeks may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months].
  - Pediatric Patients 2 to Less Than 6 Years of Age: Starting dose: 150 mg SQ every 4 weeks.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 300 mg/2 mL: 4 mL per 28 days
  - 150 mg/mL: 2 mL per 28 days

**AUTHORIZATION DURATION**: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Takhzyro will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved, Takhzyro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

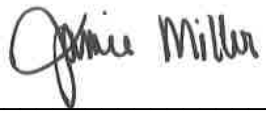
| Geisinger | POLICY NUMBER: 543.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Takhzyro |

**FORMULARY ALTERNATIVES:**
Danazol, Haegarda*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 7/25/23 – updated age to 2 years; removed danazol requirement; added dose criterion & note
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 544.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Talzenna**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Talzenna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Talzenna may be made for members who meet the following criteria:

- Medical record documentation that Talzenna is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative advanced or metastatic breast cancer as verified by a Food and Drug Administration (FDA)-approved test

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 1 capsule per day, 30 day supply per fill

**NOTE:** Information on the FDA-approved test for the detection of BRCA mutations is available at http://www.fda.gov/companiondiagnostics

**RE-AUTHORIZATION CRITERIA:** Talzenna is configured as a prior authorization for new starts only. Talzenna will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Talzenna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

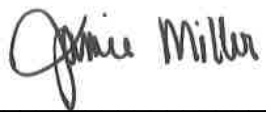
**FORMULARY ALTERNATIVES:**

Lynparza*, Zejula*, Rubraca*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Revised: 4/6/22 – updated QL for all strengths to 1 capsule per day
Revised: 3/1/23 – annual review; updated signature title
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 545.0**

**SECTION: Commercial Drug**
**SUBJECT: Qbrexza**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qbrexza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Qbrexza may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 9 years **AND**
- Medical record documentation of a diagnosis of primary axillary hyperhidrosis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prescription antiperspirant (aluminum chloride hexahydrate 6.25% [Xerac AC], 20% [Drysol])

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 per day

If a formulary exception is approved, Qbrexza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

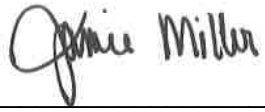
**FORMULARY ALTERNATIVES:**

Xerac AC, Drysol

| Geisinger | POLICY NUMBER: 545.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Qbrexza |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/6/19 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 546.0**

**SECTION: Commercial Drug**
**SUBJECT: Nuvessa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuvessa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nuvessa may be made for members who meet the following criteria:

- For members 18 years of age and older: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clindamycin 2% vaginal cream **AND** metronidazole 0.75% vaginal gel
- For members age 12 to less than 18 years of age: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clindamycin 2% vaginal cream

**NOTE:** Pediatric dosing is based on adult dosing for clindamycin phosphate 2% vaginal cream ONLY in postmenarchal female pediatric patients. Safety and effectiveness in premenarchal females have not been established.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

If a formulary exception is approved, Nuvessa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

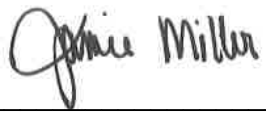
**FORMULARY ALTERNATIVES:**

clindamycin 2% vaginal cream, metronidazole 0.75% vaginal gel

| Geisinger | POLICY NUMBER: 546.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Nuvessa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/6/19 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 547.0**

**SECTION: Commercial Drug**
**SUBJECT: Alvesco and ArmonAir**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alvesco and ArmonAir for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

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3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Alvesco or ArmonAir may be made for members who meet the following criteria:

- Medical record documentation of failure on, intolerance to, or contraindication to Arnuity Ellipta **AND** QVAR RediHaler **AND** one additional formulary agent

**NOTE:** Alvesco and QVAR RediHaler are both small particle inhalers. It has been believed that the smaller particle size distribution is an advantage of these agents however there is no concrete evidence to indicate that this is clinically justified. Currently, per the guidelines, there is not one ICS inhaler preferred over the other.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Alvesco or ArmonAir will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

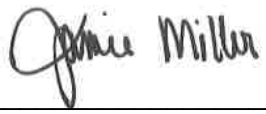
**FORMULARY ALTERNATIVES:**

Arnuity Ellipta, Asmanex, fluticasone HFA, Pulmicort Flexhaler, QVAR RediHaler

| | |
|---|---|
| Geisinger<br><br>**POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **POLICY NUMBER: 547.0**<br><br>**SECTION: Commercial Drug**<br>**SUBJECT: Alvesco and ArmonAir** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 2/6/19 |
| Reviewed: | 3/1/19 – annual review |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; updated FA |

Geisinger

**POLICY NUMBER: 548.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Daurismo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Daurismo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

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A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Daurismo may be made for members who meet the following criteria:

- Medical record documentation that Daurismo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of newly-diagnosed acute myeloid leukemia (AML) **AND**
- Medical record documentation of age 75 years or older **OR** medical record documentation of the presence of comorbidities that preclude use of intensive induction chemotherapy **AND**
- Medical record documentation that Daurismo is being used in combination with low-dose cytarabine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 100 mg tablet: 1 tablet per day, 30 day supply per fill
  - 25 mg tablet: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Daurismo is configured as a prior authorization for new starts only. Daurismo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Daurismo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

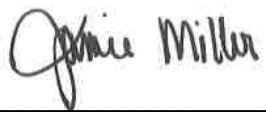
**FORMULARY ALTERNATIVES:**

Idhifa*, Tibsovo*, Venclexta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 548.0**

**SECTION: Commercial Drug**
**SUBJECT: Daurismo**

Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 549.0**

**SECTION: Commercial Drug**
**SUBJECT: Vitrakvi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vitrakvi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vitrakvi may be made for members who meet the following criteria:

- Medical record documentation that Vitrakvi is prescribed by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation **AND**
- One of the following:
    - Medical record documentation that the member must have progressed following treatment **OR**
    - Member must have no satisfactory alternative treatments

**NOTE:** There is currently no FDA-approved test for the detection of NTRK gene fusions. Testing can currently be completed via next-generation sequencing (NGS) assay and fluorescence in situ hybridization (FISH).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 25 mg capsule: 6 capsules per day, 30 day supply per fill
  - 100 mg capsule: 2 capsules per day, 30 day supply per fill
  - 20 mg/mL solution: 10 mL per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Vitrakvi is configured as a prior authorization for new starts only. Vitrakvi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Vitrakvi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 549.0**

**SECTION: Commercial Drug**
**SUBJECT: Vitrakvi**

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 550.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xospata**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xospata for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xospata may be made for members who meet the following criteria:

- Medical record documentation that Xospata is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND**
- Medical record documentation of a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by a Food and Drug Administration (FDA)-approved test

**NOTE:** Information regarding the FDA approved test for FLT3 mutations can be found at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160040C.pdf

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**RE-AUTHORIZATION CRITERIA:** Xospata is configured as a prior authorization for new starts only. Xospata will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Xospata will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

sorafenib (generic Nexavar)*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated FA; updated signature

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 550.0**

**SECTION: Commercial Drug**
**SUBJECT: Xospata**

Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 551.0**

**SECTION: Commercial Drug**
**SUBJECT: Arakoda**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Arakoda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Arakoda may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Arakoda is being prescribed for prophylaxis of malaria **AND**
- Medical record documentation of G6PD deficiency testing with documented normal levels of G6PD **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**AUTHORIZATION DURATION:** 6 months

If a formulary exception is approved, Arakoda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atovaquone/proguanil, chloroquine, doxycycline, mefloquine

| Geisinger | POLICY NUMBER: 551.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Arakoda |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/21/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 552.0**

**SECTION: Commercial Drug**
**SUBJECT: Xepi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xepi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xepi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 months **AND**
- Medical record documentation of a diagnosis of impetigo **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to mupirocin ointment **AND** oral antibiotic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** 5 days, RX count 1

If a formulary exception is approved, Xepi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

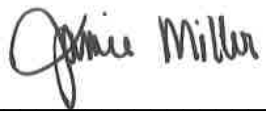
mupirocin ointment, Altabax*, cephalexin, dicloxacillin, erythromycin, clarithromycin, clindamycin, sulfamethoxazole/trimethoprim, doxycycline

*prior authorization required

| Geisinger | POLICY NUMBER: 552.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xepi |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/21/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 553.0**

**SECTION: Commercial Drug**
**SUBJECT: Tegsedi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tegsedi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tegsedi may be made for members who meet the following criteria:

- Medical record documentation that Tegsedi is prescribed by or in consultation with a neurologist, geneticist, or specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by generic testing to confirm a pathogenic mutation in TTR **AND** one of the following:
    - Biopsy of tissue/organ to confirm amyloid presence **OR**
    - A clinical manifestation typical of hATTR (neuropathy and/or congestive heart failure) without a better alternative explanation **AND**
- Medical record documentation that Tegsedi will be used to treat polyneuropathy **AND**
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden **AND**
- Medical record documentation that Tegsedi will not be used in combination with other RNA interference treatment **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

**NOTE:** Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

**NOTE:**

FAP stage:

1- unimpaired ambulation
2- assistance with ambulation
3- wheelchair-bound or bedridden

Polyneuropathy disability score:

I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
IIIa- walking with 1 stick/crutch
IIIb- walking with 2 sticks/crutches
IV- wheelchair-bound or bedridden

Polyneuropathy disability score (used in Neuro-TTR trial):

I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
III- walking with 1 stick/crutch
IV- walking with 2 sticks/crutches
V- wheelchair-bound or bedridden

If a formulary exception is approved, Tegsedi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 553.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tegsedi |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/28/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 1/5/22 – added COE criterion and note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; corrected typo

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 554.0**

**SECTION: Commercial Drug**
**SUBJECT: Firdapse**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Firdapse for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Firdapse may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that Firdapse is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of Lambert-Eaton myasthenic syndrome confirmed by one of the following:
    - Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60% compared to pre-exercise baseline value **OR**
    - Medical record documentation of high-frequency repetitive nerve stimulation (RNS) showing increase in compound muscle action potential CMAP) of at least 60% **OR**
    - Medical record documentation of positive anti-P/Q voltage-gated calcium channel antibody test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to pyridostigmine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent authorizations will be for 12 months and will require:

- Medical record documentation of clinical improvement or lack of progression in signs and symptoms of Lambert-Eaton Myasthenic Syndrome **OR**

- Medical record documentation of prescriber attestation that the member will benefit from continued therapy with Firdapse and that Firdapse treatment continues to be medically necessary

If a formulary exception is approved, Firdapse will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
pyridostigmine, guanidine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/24/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature; updated age to 6 years |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 555.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Yupelri**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Yupelri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Yupelri may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for maintenance of moderate to severe chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva **AND** Incruse Ellipta **OR**
- Medical record documentation of inability to perform proper inhaler technique

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 mL per day

If a formulary exception is approved, Yupelri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

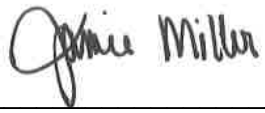
**FORMULARY ALTERNATIVES:**

Spiriva Handihaler, Spiriva Respimat, Incruse Ellipta

| Geisinger | **POLICY NUMBER: 555.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Yupelri** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/24/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 556.0**

**SECTION: Commercial Drug**
**SUBJECT: Tiglutik and Exservan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tiglutik and Exservan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tiglutik or Exservan may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tiglutik or Exservan is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to riluzole tablets **OR**
- Medical record documentation that member has dysphagia or is unable to swallow tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Exservan: 60 films per 30 days
  - Tiglutik: 600 mL per 30 days

If a formulary exception is approved, Tiglutik or Exservan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 556.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tiglutik and Exservan |

**FORMULARY ALTERNATIVES:**
riluzole tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 12/8/22 – added Exservan to policy
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 557.0**

**SECTION: Commercial Drug**
**SUBJECT: Oxtellar XR**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oxtellar XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Oxtellar XR may be made for members who meet the following criteria:

- Medical record documentation of a of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be oxcarbazepine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Oxtellar XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

For patients ≥ 6 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, topiramate IR, topiramate ER*, and pregabalin

Additional formulary alternatives for patients over certain ages: divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

Geisinger

**POLICY NUMBER: 557.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Oxtellar XR**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, added LOB table
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 558.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aemcolo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aemcolo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Aemcolo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of travelers' diarrhea **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin **AND** one oral fluoroquinolone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day

**AUTHORIZATION DURATION:** 3 days, RX count 1

If a formulary exception is approved, Aemcolo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

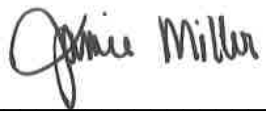
**FORMULARY ALTERNATIVES:**

azithromycin, ciprofloxacin, levofloxacin

| Geisinger | **POLICY NUMBER: 558.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Aemcolo** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/24/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 559.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Copaxone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Copaxone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Copaxone may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to glatiramer acetate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Copaxone 20 mg/mL: 30 mL per 30 days
  - Copaxone 40 mg/mL: 12 mL per 28 days

If a formulary exception is approved, Copaxone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

glatiramer acetate, fingolimod 0.5 mg, Gilenya 0.25 mg, dimethyl fumarate, Betaseron, Plegridy, Extavia, teriflunomide 14 mg, Avonex, Rebif, Mayzent

| Geisinger | POLICY NUMBER: 559.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Copaxone |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/7/22 – corrected policy number typo
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 560.0**

**SECTION: Commercial Drug**
**SUBJECT: Astagraf XL**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Astagraf XL for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Astagraf XL may be made for members who meet the following criteria:

- Medical record documentation that Astagraf XL is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation of kidney transplant **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- **If 18 years of age and older:** Medical record documentation of rationale for not using Envarsus XR if clinically appropriate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved Astagraf XL will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 560.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Astagraf XL |

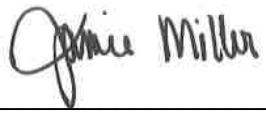
**FORMULARY ALTERNATIVES:**

tacrolimus, sirolimus*, Envarsus XR, Zortress*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 561.0**

**SECTION: Commercial Drug**
**SUBJECT: Pyrimethamine**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pyrimethamine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of pyrimethamine may be made for members who meet the following criteria:

**Treatment of Toxoplasmosis**

- Medical record documentation that pyrimethamine is prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of diagnosis of toxoplasmosis **AND**
- Medical record documentation that pyrimethamine will be used in combination with leucovorin and a sulfonamide **OR** therapeutic failure on, intolerance to, or contraindication to a sulfonamide

**AUTHORIZATION DURATION:** Initial approval will be for six (6) weeks and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of clinical syndrome (e.g. headache and/or other neurologic symptoms) **OR**
- Medical record documentation of persistent radiographic disease **OR**
- If HIV positive, medical record documentation of CD4 count less than 200 cells/microL **AND** medical record documentation that the member is taking anti-retroviral therapy (ART)

**Primary Prophylaxis of Toxoplasmosis with HIV**

- Medical record documentation that pyrimethamine is prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of diagnosis of human immunodeficiency virus (HIV) **AND**
- Medical record documentation of CD4 count less than 200 cells/microL

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to trimethoprim-sulfamethoxazole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**AUTHORIZATION DURATION:** Initial approval will be for three (3) months and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of CD4 count less than 200 cells/microL **AND**
- Medical record documentation that the member is taking anti-retroviral therapy (ART)

**NOTE:**

Recommended Dose:

- Immunocompetent patients: The recommended dose of pyrimethamine is 100 mg loading dose followed by 25 to 50 mg daily (25 mg daily for those with ocular disease).
- HIV-Treatment: The recommended initial dose of pyrimethamine 200 mg loading dose followed by 50 mg daily (<60 kg) or 75 mg daily (≥60 kg). The recommended chronic maintenance dose of pyrimethamine is 25 to 50 mg daily.
- HIV-Primary Prophylaxis: The recommended dose is 50 to 75 mg once weekly in combination with dapsone and leucovorin; or 25 mg once daily in combination with atovaquone and leucovorin.
- Congenital: The recommended dose of pyrimethamine is 2 mg/kg (maximum 50 mg/dose) once daily for two days; then 1 mg/kg (maximum 25 mg/dose) once daily for 6 months; then 1 mg/kg (maximum 25 mg/dose) three times per week for 12 months.
- Pregnancy: The recommended dose of pyrimethamine 100 mg/day orally divided into two doses for two days followed by 50 mg orally daily.

Treatment Duration:

- Immunocompetent patients with ocular disease: Minimum of 6 weeks
- HIV-Treatment: Initial- 6 weeks; chronic maintenance- 6 months or more
- HIV- Primary Prophylaxis: 3 months or more
- Congenital: 12 months
- Pregnancy: 18 weeks or after gestation and may be up administered until delivery

If a formulary exception is approved, pyrimethamine will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Treatment: none
Prophylaxis: trimethoprim-sulfamethoxazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/29/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Daraprim to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 562.0**

**SECTION: Commercial Drug**
**SUBJECT: Cablivi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cablivi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Cablivi may be made for members who meet the following criteria:

**Currently on PEX Therapy**

- Medical record documentation that Cablivi is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
- Medical record documentation that Cablivi will be used in combination with daily plasma exchange and immunosuppressive therapy (e.g. glucocorticoids, rituximab) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**Completed PEX**

- Medical record documentation that Cablivi is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
- Medical record documentation that the member previously received daily plasma exchange, immunosuppressive therapy, and Cablivi within the inpatient setting **AND**
- Medical record documentation of the date of the last plasma exchange **AND**
    - Medical record documentation of one of the following:
        - The date of plasma exchange is within 30 days of the request date **OR**
        - If the date of plasma exchange is > 30 days of the request date, medical record documentation sign(s) of persistent underlying disease

(e.g., suppressed ADAMTS13 activity levels remain present) and medical record documentation that the member has not exceeded the maximum treatment duration of Cablivi (30 days post PEX and up to 28 days of extended treatment) **AND**

- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 kit per day

**AUTHORIZATION DURATION:** Initial approval will be for 30 days or less if the reviewing provider feels it is medically necessary. Subsequent approvals will be for an additional 30 days or less if the reviewing provider feels it is medically necessary. Requests for continuation of coverage will be approved for members who meet the following criteria:

**Currently on PEX Therapy**

- Medical record documentation that the member is still receiving daily plasma exchange therapy and Cablivi will be used in combination with plasma exchange and immunosuppressive therapy (e.g. glucocorticoids, rituximab) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**Completed PEX within 30 days**

- Medical record documentation that the member previously received daily plasma exchange and immunosuppressive therapy **AND**
- Medical record documentation of the date of last plasma exchange **AND**
- The date of plasma exchange is within 30 days of the request date **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**Completed PEX greater than 30 days**

- Medical record documentation sign(s) of persistent underlying disease (e.g. suppressed ADAMTS13 activity levels remain present) **AND**
- Medical record documentation of the date of last plasma exchange **AND**
- Medical record documentation that the member has not exceeded the maximum treatment duration of Cablivi (30 days post PEX and up to 28 days of extended treatment) **AND**

- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**NOTE:** Cablivi should be administered upon initiation of PEX therapy, during daily PEX, and continued daily for 30 days following last daily PEX. If necessary, treatment can be extended for a maximum of 28 days.

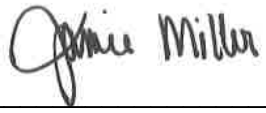
If a formulary exception is approved, Cablivi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 563.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Balversa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Balversa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Balversa may be made for members who meet the following criteria:

- Medical record documentation that Balversa is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of an FGFR3 genetic alteration determined using a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on or after one line of prior systemic therapy

**NOTE:** The FDA-approved test is the *therascreen*® FGFR RGQ RT-PCR Kit

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 3 mg tablet – 3 tablets per day, 28 day supply per fill
  - 4 mg tablet – 2 tablets per day, 28 day supply per fill
  - 5 mg tablet – 1 tablet per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Balversa is configured as a prior authorization for new starts only. Balversa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Balversa will be paid for under the member's prescription drug benefit.

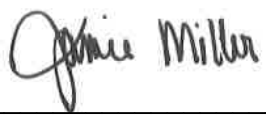
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Geisinger

**POLICY NUMBER: 563.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Balversa**

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |
| Revised: | 4/10/24 – removed FGFR2 alteration; updated failure of platinum therapy to one prior systemic |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 564.0**

**SECTION: Commercial Drug**
**SUBJECT: Symjepi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symjepi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Symjepi may be made for members who meet the following criteria:

- Medical record documentation that the patient has shown the inability to properly use the generic EpiPen device

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 pens per fill

**NOTE:** In the event that the preferred alternative is unavailable at the time of the request, exception can be made to approve the use of Symjepi for an appropriate length of time as designated by the reviewer.

If a formulary exception is approved, Symjepi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

epinephrine auto-injector (generic EpiPen)

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 564.0**

**SECTION: Commercial Drug**
**SUBJECT: Symjepi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 565.0**

**SECTION: Commercial Drug**
**SUBJECT: Diacomit**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Diacomit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Diacomit may be made for members who meet the following criteria:

- Medical record documentation that Diacomit is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 6 months **AND**
- Medical record documentation of weight greater than or equal to 7 kilograms **AND**
- Medical record documentation of a diagnosis of Dravet syndrome **AND**
- Medical record documentation that Diacomit is to be used in combination with clobazam

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

If a formulary exception is approved, Diacomit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

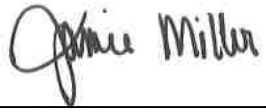
| Geisinger | POLICY NUMBER: 565.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Diacomit |

**FORMULARY ALTERNATIVES:**

clobazam, divalproex, divalproex ER, valproic acid, levetiracetam, levetiracetam ER topiramate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 10/6/22 – updated age to 6 months; added weight criterion |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | **POLICY NUMBER: 566.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Piqray** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Piqray for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Piqray may be made for members who meet the following criteria:

- Medical record documentation that Piqray is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive, HER2-negative (HR+/HER2-) **AND**
- Medical record documentation of a PIK3CA mutation determined using a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to prior endocrine therapy **AND**
- Medical record documentation that Piqray is being prescribed in combination with fulvestrant

**NOTES:** The FDA-approved test is the *therascreen*® PIK3CA RGQ PCR Kit.

Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 300 mg or 250 mg daily dose: 2 tablets per day, 28 day supply per fill
  - 200 mg daily dose: 1 tablet per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Piqray is configured as a prior authorization for new starts only. Piqray will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Piqray will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

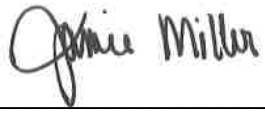
anastrozole, letrozole, exemestane, tamoxifen, raloxifene, sirolimus, everolimus (generic Afinitor)*, Kisqali*, Kisqali-Femara*, Ibrance*, Verzenio*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 566.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Piqray** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |
| Revised: | 4/10/24 – removed male/postmenopausal female criterion; updated auth entry to 1 month duration |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 567.0**

**SECTION: Commercial Drug**
**SUBJECT: Inveltys, Loteprednol Suspension, Lotemax Gel, & Lotemax SM**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inveltys, loteprednol suspension, Lotemax gel, and Lotemax SM for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Inveltys, loteprednol, Lotemax Gel, or Lotemax SM may be made for members who meet the following criteria:

**For Inveltys, Lotemax Gel, and Lotemax SM**

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**For loteprednol suspension**

- Medical record documentation for treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe **OR**
- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**OR**

- Medical record documentation for use of a medically accepted indication for the short-term treatment of the signs and symptoms of dry eye disease

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only if request is for loteprednol suspension

If a formulary exception is approved, Inveltys, loteprednol, Lotemax Gel, or Lotemax SM will be paid for under the member's prescription drug benefit.

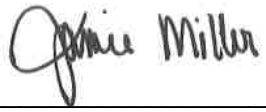
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, bromfenac 0.09%, ketorolac drops 0.4% and 0.5%, diclofenac sodium 0.1%, Maxidex, FML S.O.P.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 8/1/19 – added missing comma |
| Revised: | 9/20/19 – added inflammatory conditions indication for loteprednol suspension |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/6/22 – added dry eye indication to loteprednol |
| Revised: | 3/1/23 – annual review; added generic only approval language for loteprednol suspension; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 568.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Motegrity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Motegrity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Motegrity may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic idiopathic constipation **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Linzess

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Motegrity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

lubiprostone, Linzess

| Geisinger | POLICY NUMBER: 568.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Motegrity |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Amitiza to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 569.0**

**SECTION: Commercial Drug**
**SUBJECT: Fosfomycin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for fosfomycin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of fosfomycin may be made for members who meet the following criteria:

**Uncomplicated Cystitis**

- Medical record documentation of use for treatment of uncomplicated cystitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to, or bacterial resistance to nitrofurantoin **AND** sulfamethoxazole-trimethoprim

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 1 dose

**AUTHORIZATION DURATION:** one-time approval, RX count 1

**Uncomplicated Cystitis caused by ESBL or Multidrug Resistant Bacteria**

- Medical record documentation of use for treatment of uncomplicated cystitis **AND**
- Medical record documentation of ESBL-producing bacteria or multidrug resistant bacteria **AND**
- Medical record documentation of susceptibility to fosfomycin **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative oral antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

| Geisinger | POLICY NUMBER: 569.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Fosfomycin** |

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 3 doses

**AUTHORIZATION DURATION**: 9 days, RX count 1

**NOTE:** There is little to no evidence supporting use of fosfomycin as prophylaxis.

If a formulary exception is approved, fosfomycin will be paid for under the member's prescription drug benefit.

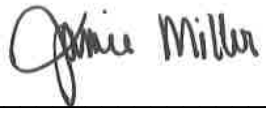
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

nitrofurantoin, sulfamethoxazole-trimethoprim

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Monurol to generic |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; added generic only approval |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 570.0**

**SECTION: Commercial Drug**
**SUBJECT: Follistim AQ**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Follistim AQ for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Follistim AQ may be made for members who meet the following criteria:

**For Females:**

- Medical record documentation that Follistim AQ is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Poor/diminished ovarian reserve **OR**
  - Tubal factor infertility **OR**
  - Follistim AQ is being used with donor eggs **OR**
  - In Vitro Fertilization **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f

**OR**

- Medical record documentation that Follistim AQ is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that infertility is not due to primary ovarian failure **AND**
- Medical record documentation that Follistim AQ is being using concomitantly with an hCG product **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f **AND**
- For patients without a diagnosis of hyperprolactinemic anovulation:
  - Medical record documentation of therapeutic failure, contraindication, or intolerance to clomiphene and/or letrozole for a total of 3 cycles **OR**

- For patients with a diagnosis of hyperprolactinemic anovulation, one of the following:
  - Uncorrected prolactin levels, greater than 25 ng/mL, after 6 months of therapy on bromocriptine or cabergoline **OR**
  - Corrected prolactin levels, less than or equal to 25 ng/mL, on bromocriptine or cabergoline with therapeutic failure, contraindication, or intolerance to 3 cycles of clomiphene and/or letrozole

**For Males:**

- Medical record documentation that Follistim AQ is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of male factor infertility **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Follistim AQ will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

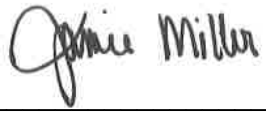
**FORMULARY ALTERNATIVES:**

Gonal-f

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 570.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Follistim AQ** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/20/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 572.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Human Chorionic Gonadotropin (hCG)** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for human chorionic gonadotropin (hCG) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of human chorionic gonadotropin (hCG) may be made for members who meet the following criteria:

- Medical record documentation that human chorionic gonadotropin (hCG) is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for ovulation induction in females **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

**OR**

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (hypogonadotropic hypogonadism in males or prepubertal cryptorchidism) **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, human chorionic gonadotropin (hCG) will be paid for under the member's prescription drug benefit.

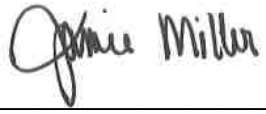
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 572.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Human Chorionic Gonadotropin (hCG) |

**FORMULARY ALTERNATIVES:**
Pregnyl

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 573.0**

**SECTION: Commercial Drug**
**SUBJECT: Novarel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Novarel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Novarel may be made for members who meet the following criteria:

- Medical record documentation that Novarel is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for ovulation induction in females **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

**OR**

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (hypogonadotropic hypogonadism in males or prepubertal cryptorchidism) **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

**MEDISPAN AUTHORIZATION LEVEL:** NDC-9 (must enter 555661501 & 555661502)

If an exception is made, Novarel will be paid for under the member's prescription drug benefit.

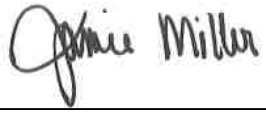
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 573.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Novarel |

**FORMULARY ALTERNATIVES:**
Pregnyl

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 574.0**

**SECTION: Commercial Drug**
**SUBJECT: Crinone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Crinone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Crinone may be made for members who meet the following criteria:

- Medical record documentation of use for secondary amenorrhea

**OR**

- Medical record documentation of use as part of assisted reproductive technology (ART) **AND**
- Medical record documentation of use of Crinone 8% gel **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Endometrin

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Crinone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

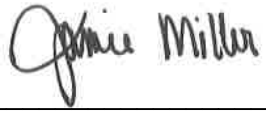
**FORMULARY ALTERNATIVES:**

Endometrin

| Geisinger | **POLICY NUMBER: 574.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Crinone** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/23/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 575.0**

**SECTION: Commercial Drug**
**SUBJECT: Difluprednate (generic Durezol)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for difluprednate (generic Durezol) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of difluprednate (generic Durezol) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of uveitis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to prednisolone acetate 1%

**OR**

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved, difluprednate (generic Durezol) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 575.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Difluprednate<br>(generic Durezol) |

**FORMULARY ALTERNATIVES:**

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, bromfenac 0.09%, ketorolac drops 0.4% and 0.5%, diclofenac sodium 0.1%, Maxidex, FML S.O.P.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 3/1/24 – annual review; updated to generic only |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 576.0**

**SECTION: Commercial Drug**
**SUBJECT: Loteprednol (generic Alrex)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for loteprednol (generic Alrex) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of loteprednol (generic Alrex) may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of allergic conjunctivitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following formulary alternatives: azelastine ophthalmic drops, epinastine, ophthalmic drops, **OR** olopatadine ophthalmic drops **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary steroid **OR** non-steroidal anti-inflammatory drug (NSAID) eye drop alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

If a formulary exception is approved, loteprednol (generic Alrex) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

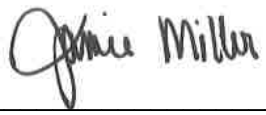
**FORMULARY ALTERNATIVES:**

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, ketorolac drops 0.5%, Maxidex, FML S.O.P., azelastine drops 0.05%, epinastine drops 0.05%, olopatadine drops 0.1% and 0.2%

| Geisinger | POLICY NUMBER: 576.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Loteprednol (generic Alrex) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; updated to generic only |

Geisinger

**POLICY NUMBER: 577.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Pred Mild**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pred Mild for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Pred Mild may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of a steroid responsive inflammatory condition of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to three (3) formulary alternatives

**OR**

- Medical record documentation of a diagnosis of corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to prednisolone acetate 1% **OR** prednisolone acetate 1% (P-F) **AND** dexamethasone sodium phosphate 0.1%

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

If a formulary exception is approved, Pred Mild will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 577.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Pred Mild |

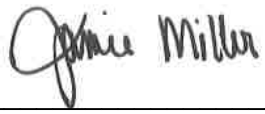
**FORMULARY ALTERNATIVES:**

Steroid responsive inflammatory condition: dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate 1% (P-F), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, Maxidex, FML S.O.P.

Corneal injury: prednisolone acetate 1% (P-F), dexamethasone sodium phosphate 0.1%

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 578.0**

**SECTION: Commercial Drug**
**SUBJECT: Acuvail, Bromfenac (generic BromSite or Prolensa), Ilevro, And Nevanac**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Acuvail, bromfenac (generic BromSite or Prolensa), Ilevro, and Nevanac for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Acuvail, bromfenac (generic BromSite or Prolensa), Ilevro, or Nevanac may be made for members who meet the following criteria:

- Medical record documentation of use for postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, if request is for bromfenac include generic only

If a formulary exception is approved, Acuvail, bromfenac (generic BromSite or Prolensa), Ilevro, or Nevanac will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, bromfenac 0.09%, ketorolac drops 0.4% and 0.5%, diclofenac sodium 0.1%, Maxidex, FML S.O.P.

| Geisinger | POLICY NUMBER: 578.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Acuvail, Bromfenac (generic BromSite or Prolensa), Ilevro, And Nevanac |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated BromSite and Prolensa to generic only

Geisinger

**POLICY NUMBER: 579.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Mavenclad**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mavenclad for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Mavenclad may be made for members who meet the following criteria:

- Medical record documentation that Mavenclad is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsing form of multiple sclerosis including relapsing-remitting disease and active secondary progressive disease **AND**
  *Note: Mavenclad is not indicated for the clinically isolated syndrome subtype of multiple sclerosis.*
- Medical record documentation that Mavenclad will be used as monotherapy **AND**
- Medical record documentation that the prescribed dose is appropriate for member's weight **AND**
- Medical record documentation that member has not been treated with more than three (3) previous treatment cycles of Mavenclad for relapsing forms of multiple sclerosis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives for the treatment of multiple sclerosis

**NOTE:** Cumulative use of Mavenclad for more than two years (4 cycles) of treatment during a member's lifetime has not been evaluated.

| | Weight Range (kg) | First Cycle | Second Cycle |
|---|---|---|---|
| Dose of Mavenclad per cycle by member weight in each treatment course. | 40* to less than 50 | 40 mg (4 tablets) | 40 mg (4 tablets) |
| | 50 to less than 60 | 50 mg (5 tablets) | 50 mg (5 tablets) |
| | 60 to less than 70 | 60 mg (6 tablets) | 60 mg (6 tablets) |
| | 70 to less than 80 | 70 mg (7 tablets) | 70 mg (7 tablets) |
| | 80 to less than 90 | 80 mg (8 tablets) | 70 mg (7 tablets) |
| | 90 to less than 100 | 90 mg (9 tablets) | 80 mg (8 tablets) |
| | 100 to less than 110 | 100 mg (10 tablets) | 90 mg (9 tablets) |
| | 110 and above | 100 mg (10 tablets) | 100 mg (10 tablets) |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:

| Dosage | Quantity Limit |
|---|---|
| 40 mg | 4 tablets per 27 days |
| 50 mg | 5 tablets per 28 days |
| 60 mg | 6 tablets per 28 days |
| 70 mg | 7 tablets per 28 days |
| 80 mg | 8 tablets per 28 days |
| 90 mg | 9 tablets per 28 days |
| 100 mg | 10 tablets per 28 days |

**AUTHORIZATION DURATION:** The initial authorization will be for 48 weeks with an RX Count of 2. One subsequent authorization will be for 48 weeks with an RX Count of 2 and will require the following:

- Medical record documentation that member has not received more than three previous cycles of Mavenclad treatment for relapsing forms of multiple sclerosis **AND**
- Medical record documentation that member has not experienced unacceptable toxicity or worsening of disease

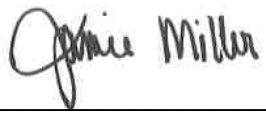
**FORMULARY ALTERNATIVES:**

glatiramer acetate, fingolimod 0.5 mg capsule, Gilenya 0.25 mg, dimethyl fumarate, Betaseron, Plegridy, Extavia, teriflunomide 14 mg, Avonex, Rebif, Mayzent

| Geisinger | POLICY NUMBER: 579.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Mavenclad |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Revised: | 3/1/24 – annual review; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 580.0**

**SECTION: Commercial Drug**
**SUBJECT: Skyrizi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Skyrizi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Skyrizi may be made for members who meet the following criteria:

**For treatment of plaque psoriasis**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Skyrizi is prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- **Prefilled Syringe Kit 75 mg/0.83 mL, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
  - In PA Hub: Add Treat As "Include" Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
    - QL FOR LETTER: Loading dose: 1 kit per 28 days; Maintenance dose: 1 kit per 84 days
- **Prefilled 150 mg/mL Syringe or Auto-Injector, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
  - In PA Hub: Add Treat As "Include" Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
    - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

**RE-AUTHORIZATION CRITERIA:** Skyrizi is configured as a prior authorization for new starts only. Skyrizi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

cyclosporine, methotrexate
**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF);

betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**For treatment of psoriatic arthritis**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Skyrizi is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of one of the following:
    - For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- **Prefilled Syringe Kit 75 mg/0.83 mL, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
    - In PA Hub: Add Treat As “Include” Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
        - QL FOR LETTER: Loading dose: 1 kit per 28 days; Maintenance dose: 1 kit per 84 days
- **Prefilled 150 mg/mL Syringe or Auto-Injector, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
    - In PA Hub: Add Treat As “Include” Process Modifier, Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
        - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

**RE-AUTHORIZATION CRITERIA:** Skyrizi is configured as a prior authorization for new starts only. Skyrizi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**For treatment of Crohn's disease**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Skyrizi is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and immunomodulators (e.g. azathioprine and 6 mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/ or penetrating behavior

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- **Subcutaneous Solution Cartridge 360 mg/2.4 mL, Skyrizi 600 mg IV at weeks 0, 4, and 8 then 360 mg at week 12 and every 8 weeks thereafter**
    - In PA Hub: Add Treat As "Include" Process Modifier, max number of claims authorized 1, max quantity dispensed 2.4, with a duration of one month.
        - QL FOR LETTER: 2.4 mL per 56 days

**RE-AUTHORIZATION CRITERIA:** Skyrizi is configured as a prior authorization for new starts only. Skyrizi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 105 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

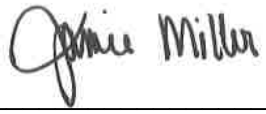
Corticosteroids: prednisone, budesonide
Immunomodulators: azathioprine, 6-mercaptopurine

If a formulary exception is approved Skyrizi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 11/5/19 – corrected typo, adjusted QL |
| Revised: | 3/1/20 – annual review, added GHP Kids, updated QL statement |
| Revised: | 3/1/21 – annual review, updated logo, updated QL statement, added MediSpan approval level |
| Revised: | 7/1/21 – add QL for 150 mg syringe/autoinjector |
| Revised: | 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO |
| Revised: | 1/5/22 – added OUP override to authorization |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered |
| Revised: | 6/7/22 – added PsA indication |
| Revised: | 1/1/23 – added CD indication; removed failure of Cosentyx/Humira from PsO & PsA; added first line therapy failure to PsO; & PsA; updated PsO & PsA FA |
| Revised: | 3/1/23 – annual review; corrected typo in CD QL; updated lookback to 105 days; updated signature title |
| Revised: | 3/1/24 – annual review; updated auth entry parameters |

| Geisinger | POLICY NUMBER: 581.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Rocklatan** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rocklatan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Rocklatan may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be a prostaglandin analog

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.17 mL per day

**NOTE:** There are certain ocular inflammatory conditions including iritis and uveitis which do not warrant the use of Prostaglandin eye drops as first line therapy.

If a formulary exception is approved, Rocklatan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

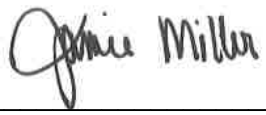
brimonidine, latanoprost, timolol, tafluprost*, travoprost, Alphagan P, brinzolamide, Vyzulta*, bimatoprost 0.03%*, Lumigan 0.01%*, Rhopressa*, Simbrinza, Combigan

*prior authorization or step therapy required

| Geisinger | POLICY NUMBER: 581.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Rocklatan |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Revised: | 3/1/24 – annual review; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 582.0**

**SECTION: Commercial Drug**
**SUBJECT: Vyndaqel and Vyndamax**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vyndaqel and Vyndamax for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vyndaqel or Vyndamax may be made for members who meet the following criteria:

- Medical record documentation that Vyndaqel or Vyndamax is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of cardiomyopathy resulting from wild type transthyretin-mediated amyloidosis **OR** hereditary transthyretin-mediated amyloidosis as confirmed by ONE of the following:
    - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD *(Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)* **OR**
    - Biopsy of tissue of the affected organ to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

**AND**

- Medical record documentation that the patient has New York Heart Association (NYHA) Class I, II, or III heart failure **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

**NOTE:** Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Vyndaqel – 4 tablets per day, 30 day supply per fill
  - Vyndamax – 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months, requiring prescriber attestation that the patient continues to benefit from tafamidis therapy. The medication will no longer be covered if the member experiences toxicity or progresses to NYHA class IV heart failure.

If a formulary exception is approved, Vyndaqel or Vyndamax will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 1/5/22 – added COE criterion and note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; corrected typo in Vyndaqel QL; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 583.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Duobrii**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Duobrii for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Duobrii may be made for members who meet the following criteria:

- Medical record documentation that Duobrii is prescribed by or in consultation with a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to tazarotene used in combination with three (3) different topical corticosteroids

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Duobrii will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

tazarotene

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 583.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Duobrii** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/25/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 7/20/22 – updated topical corticosteroid alternatives |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 585.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nubeqa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nubeqa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Nubeqa may be made for members who meet the following criteria:

- Medical record documentation that Nubeqa is prescribed by an oncologist or urologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that members is receiving GnRH analog(s) concurrently **OR** that member has had a bilateral orchiectomy **AND**
- Medical record documentation of one of the following:
    - a diagnosis of non-metastatic, castration-resistant prostate cancer **OR**
    - a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** Nubeqa is being used in combination with docetaxel

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Nubeqa is configured as a prior authorization for new starts only. Nubeqa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Nubeqa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

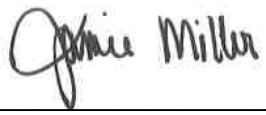
**FORMULARY ALTERNATIVES:**

Erleada*, Xtandi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/27/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 12/27/22 – added mHSPC indication

Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 586.0**

**SECTION: Commercial Drug**
**SUBJECT: Turalio**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Turalio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Turalio may be made for members who meet the following criteria:

- Medical record documentation that Turalio is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of tenosynovial giant cell tumor that meets both of the following criteria:
    - associated with functional limitations or severe morbidity **AND**
    - not amenable to improvement with surgery

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Turalio is configured as a prior authorization for new starts only. Turalio will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Turalio will be paid for under the member's prescription drug benefit.

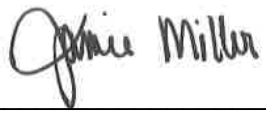
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/27/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 587.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sunosi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sunosi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Sunosi may be made for members who meet the following criteria:

**Narcolepsy**

- Medical record documentation of a diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to: modafinil* or armodafinil* **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

**Obstructive Sleep Apnea**

- Medical record documentation of a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member's underlying airway obstruction has been treated (e.g., with a continuous positive airway pressure (CPAP)) for at least one month prior to the initiation of Sunosi **AND**
- Medical record documentation that the member will continue to use this treatment modality (e.g., CPAP) while received Sunosi **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to: modafinil* **OR** armodafinil*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Sunosi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

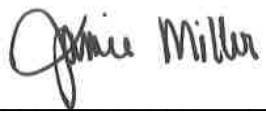
For Narcolepsy: dextroamphetamine/amphetamine, dextroamphetamine, methylphenidate, armodafinil*, modafinil*, Xywav*, sodium oxybate oral solution (generic Xyrem)*

For Obstructive Sleep Apnea: armodafinil*, modafinil*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Revised: 3/1/23 – annual review; updated FA; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY NUMBER: 588.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Rozlytrek**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rozlytrek for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Rozlytrek may be made for members who meet the following criteria:

**NTRK-Fusion Positive Solid Tumors**

- Medical record documentation that Rozlytrek is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation **AND**
- One of the following:
  - Medical record documentation that the member must have progressed following treatment **OR**
  - Medical record documentation that no satisfactory alternative treatments are available

**ROS1-Positive Non-Small Cell Lung Cancer**

- Medical record documentation that Rozlytrek is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS1*-positive

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 100 mg capsules: 1 capsule per day, 30 day supply per fill
  - 200 mg capsules: 3 capsules per day, 30 day supply per fill
  - 50 mg packets: 12 packets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rozlytrek is configured as a prior authorization for new starts only. Rozlytrek will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Rozlytrek will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

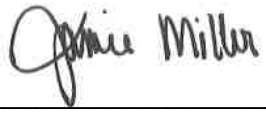
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 588.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Rozlytrek** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/20/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL Statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 2/12/24 – removed age criterion from NTRK tumors; added QL for packets; updated to GPI-10 |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 589.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Inrebic** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inrebic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Inrebic may be made for members who meet the following criteria:

- Medical record documentation that Inrebic is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of intermediate-2 (INT-2) or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count greater than or equal to 50 x $10^9$/L **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of baseline total symptom score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Inrebic will not be used concurrently with Jakafi **AND**
- Medical record documentation that the member is ineligible for allogenic hematopoietic cell transplantation

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Inrebic will no longer be covered if medical record documentation does not show:

- Medical record documentation of platelet count greater than or equal to 50 x $10^9$/L **AND**
- The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

**NOTE:** Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

- Age > 65 years
- WBC > 25 x 109/L
- Hemoglobin < 10 g/dL
- Blood Blasts ≥ 1%
- Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- Transfusion dependency
- Platelets less than 100 X 109/L
- Unfavorable karyotype

If a formulary exception is approved, Inrebic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Jakafi*

*prior authorization required

| Geisinger | POLICY NUMBER: 589.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Inrebic |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 590.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nuzyra**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuzyra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nuzyra may be made for members who meet the following criteria:

- Medical record documentation that Nuzyra is prescribed by or in consultation with infectious disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Diagnosis of Community-acquired bacterial pneumonia caused by *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae, Legionella pneumophila*, *Mycoplasma pneumoniae, and Chlamydophila pneumoniae* **OR**
    - Diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes, Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae,* and *Klebsiella pneumoniae* **AND**
- Medical record documentation of a culture and sensitivity showing the member's infection is not susceptible to alternative antibiotic treatment **OR** documented history of previous intolerance to or contraindication to three (3) alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that treatment with Nuzyra was initiated during an inpatient stay

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 30 tablets per 14 days

**AUTHORIZATION DURATION:** 14 days

If a formulary exception is approved, Nuzyra will be paid for under the member's prescription drug benefit.

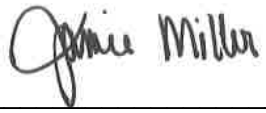
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

amoxicillin, azithromycin, cephalexin, clarithromycin, doxycycline, erythromycin, levofloxacin, linezolid, moxifloxacin, penicillin, vancomycin capsules, Firvanq

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 591.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Nayzilam |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nayzilam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nayzilam may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years
  **OR**
- Medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature **AND**
- For members at least 2 years of age: medical record documentation of why diazepam rectal gel cannot be used

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 nasal spray units per 30 days

If a formulary exception is approved, Nayzilam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

diazepam rectal gel

| Geisinger | POLICY NUMBER: 591.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Nayzilam |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/20/19 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 592.0**

**SECTION: Commercial Drug**
**SUBJECT: Nucala for Self-Administration**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nucala for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nucala for self-administration may be made for members who meet the following criteria:

**Severe Eosinophilic Asthma**

- Medical record documentation that Nucala is prescribed by an allergist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma **AND** that Nucala is being used as add-on maintenance treatment **AND**
- Medical record documentation of a blood eosinophil count of either greater than 300 cells/mcL during the 12-month period before screening and/or greater than 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
    - intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3- month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that member is adherent to current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Nucala will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Xolair, Fasenra, Dupixent, Cinqair, or Tezspire)

*Measures of disease severity

| Measure | Not Well Controlled | Very Poorly Controlled |
|---|---|---|
| Symptoms | > 2 days per week | Throughout the day |
| Nighttime awakenings | 1-3x/week | > 4x/week |
| Interference with normal activity | Some limitation | Extremely limited |
| SABA use for symptom control (not to prevent exercise-induced bronchospasm) | > 2 days/week | Several times per day |
| FEV1 (% predicted) or peak flow (% personal best) | 60-80% | < 60% |
| Asthma Control Test (ACT) Score | 16-19 | < 15 |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 1 prefilled syringe or autoinjector per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Eosinophilic Granulomatosis (EGPA)**

- Medical record documentation that Nucala is prescribed by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis **AND** at least four (4) of the following criteria:
    - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
    - Eosinophilia (blood eosinophil level of greater than or equal to 10% or greater than or equal to 1500 cells/microL on differential white blood cell count)
    - Mononeuropathy (including multiplex) or polyneuropathy
    - Migratory or transient pulmonary opacities detected radiographically
    - Paranasal sinus abnormality
    - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

**AND**

- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy **AND** at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 3 prefilled syringes or 3 autoinjectors (300 mg) per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Hypereosinophilic Syndrome (HES)**

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRα) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**
- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**
- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 3 prefilled syringes or 3 autoinjectors (300 mg) per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

- Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Nucala will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 1 prefilled syringe or 1 autoinjector (100 mg) per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**FORMULARY ALTERNATIVES:**

Severe Eosinophilic Asthma: dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, fluticasone HFA, Pulmicort Flexhaler, QVAR RediHaler

EGPA: dexamethasone, methylprednisolone, prednisone, cyclophosphamide, azathioprine, methotrexate

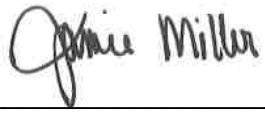
CRSwNP: fluticasone propionate, triamcinolone acetonide, mometasone furoate

If a formulary exception is approved, Nucala for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added HES indication
Revised: 1/5/22 – added CRSwNP indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – added prescribers for CRSwNP
Revised: 6/7/22 – updated concurrent biologic criterion in asthma indication
Revised: 6/27/22 – updated asthma age to 6 years and QL to include all doses

Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 593.0**

**SECTION: Commercial Drug**
**SUBJECT: Fasenra for Self-Administration**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fasenra for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Fasenra for self-administration may be made for members who meet the following criteria:

- Medical record documentation that Fasenra is prescribed by an allergist/immunologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma **AND** that Fasenra is being used as add-on maintenance treatment **AND**
- Medical record documentation of a blood eosinophil count greater than 150 cells/mcL (0.15 x 10E3/uL) within the past 3 months **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3-month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that member is adherent to current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Fasenra will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Xolair, Dupixent, Nucala, Cinqair, or Tezspire)

*Measures of disease severity

| Measure | Not Well Controlled | Very Poorly Controlled |
|---|---|---|
| Symptoms | > 2 days per week | Throughout the day |
| Nighttime awakenings | 1-3x/week | > 4x/week |
| Interference with normal activity | Some limitation | Extremely limited |
| SABA use for symptom control (not to prevent exercise-induced bronchospasm) | > 2 days/week | Several times per day |
| FEV1 (% predicted) or peak flow (% personal best) | 60-80% | < 60% |
| Asthma Control Test (ACT) Score | 16-19 | < 15 |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:**

- **Initial Approval –** *Two authorizations must be entered.*
    - Fasenra 30 mg every 4 weeks for the first 3 doses, then once every 8 weeks
        1. In PA Hub: Add PA only.
        2. In Darwin: Add OQL, DS, max number of claims authorized 3, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of 3 months.
            - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 56 days
- **Renewal –** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
            - QL FOR LETTER ONLY: 1 mL per 56 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Documentation that patient is not experiencing toxicity or worsening of disease **AND**
- Medical record documentation of at least one of the following:
    - Medical record documentation of continued disease improvement or lack of disease progression as evidenced by a reduction in asthma exacerbations (e.g. reduced use of rescue medications, reduced urgent care visits, reduced hospitalizations) **OR**

- Medical record documentation of decreased oral corticosteroid use (if on maintenance treatment prior to Fasenra initiation)

If a formulary exception is approved, Fasenra for self-administration will be paid for under the member's prescription drug benefit.

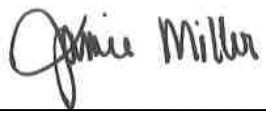
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, fluticasone HFA, Pulmicort Flexhaler, QVAR RediHaler

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered
Revised: 6/7/22 – updated concurrent biologic criterion in asthma indication
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 595.0**

**SECTION: Commercial Drug**
**SUBJECT: Bijuva**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bijuva for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Bijuva may be made for members who meet the following criteria:

- Medical record documentation of use for treatment of moderate to severe vasomotor symptoms due to menopause **AND**
- Medical record documentation of an intact uterus **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to estradiol used in combination with progesterone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Bijuva will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

estradiol (tablets, patches, cream), estradiol/norethindrone, Fyavolv, Lopreeza, medroxyprogesterone, Mimvey Lo, northethindrone/ethinyl estradiol, progesterone, Combipatch, Premarin, Prempro, Premphase

| Geisinger | POLICY NUMBER: 595.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Bijuva |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/16/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 596.0**

**SECTION: Commercial Drug**
**SUBJECT: Cequa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cequa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Cequa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of keratoconjunctivitis sicca (dry eye) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Xiidra (lifitegrast) **AND** cyclosporine (generic Restasis)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 vials per day

If a formulary exception is approved, Cequa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

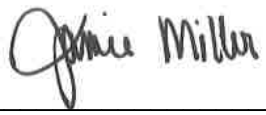
**FORMULARY ALTERNATIVES:**

cyclosporine ophthalmic emulsion (generic Restasis), Xiidra

| Geisinger | POLICY NUMBER: 596.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Cequa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 3/1/24 – annual review; updated Restasis to generic only |

Geisinger

**POLICY NUMBER: 597.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Drizalma**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Drizalma for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Drizalma may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
  - Medical record documentation major depressive disorder, diabetic peripheral neuropathic pain, chronic musculoskeletal pain, or fibromyalgia in member age greater than or equal to 18 years **OR**
  - Medical record documentation of generalized anxiety disorder in members age greater than or equal to 7 years

**AND**

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be duloxetine capsules

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day

If an exception is made, Drizalma will be paid for under the member's prescription drug benefit.

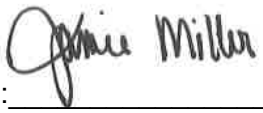
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Major depressive disorder: duloxetine capsules, amitriptyline, bupropion, citalopram, desvenlafaxine, doxepin, escitalopram, fluoxetine, mirtazapine, nortriptyline, phenelzine, sertraline, trazodone, venlafaxine, desvenlafaxine
Diabetic peripheral neuropathic pain: duloxetine capsules, pregabalin solution
Chronic musculoskeletal pain: duloxetine capsules
Fibromyalgia: duloxetine capsules, pregabalin solution, Savella
Generalized Anxiety Disorder: duloxetine capsules, escitalopram, paroxetine, venlafaxine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/1/21 – added fibromyalgia indication, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 598.0**

**SECTION: Commercial Drug**
**SUBJECT: Ezallor**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ezallor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ezallor may be made for members who meet the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to up to three (3) formulary statins of the same prescribed intensity*, one of which must be rosuvastatin

*High-, Moderate-, and Low-Intensity Statin Therapy

| | High Intensity | Moderate Intensity | Low Intensity |
|---|---|---|---|
| LDL-C lowering | ≥50% | 30%–49% | <30% |
| Statins | Atorvastatin 40 mg, 80 mg<br>Rosuvastatin 20 mg, 40 mg | Atorvastatin 10 mg, 20 mg<br>Rosuvastatin 5 mg, 10 mg<br>Simvastatin 20–40 mg | Simvastatin 10 mg |
| | | Pravastatin 40 mg, 80 mg<br>Lovastatin 40 mg, 80 mg<br>Fluvastatin XL 80 mg<br>Fluvastatin 40 mg BID<br>Pitavastatin 1–4 mg | Pravastatin 10–20 mg<br>Lovastatin 20 mg<br>Fluvastatin 20–40 mg |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

If a formulary exception is approved Ezallor will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 598.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ezallor |

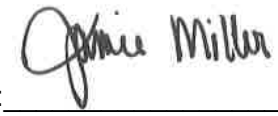
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 7/25/23 – updated FA criterion to require statin; added note |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 599.0**

**SECTION: Commercial Drug**
**SUBJECT: Kapspargo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kapspargo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Kapspargo may be made for members who meet the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of use through nasogastric tube **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary beta-blocking agents, one of which must be metoprolol succinate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 25 mg, 50 mg, and 100 mg capsule: 1 capsule per day
  - 200 mg capsule: 2 capsules per day

If a formulary exception is approved Kapspargo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 599.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Kapspargo |

**FORMULARY ALTERNATIVES:**

acebutolol, atenolol-chlorthalidone, betaxolol, bisoprolol, bisoprolol-hydrochlorothiazide, carvedilol, labetalol, metoprolol succinate, metoprolol-hydrochlorothiazide, nadolol, nadolol-bendroflumethiazide, pindolol, propranolol, propranolol-hydrochlorothiazide, sotalol, timolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/17/20
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 601.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Siklos**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Siklos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Siklos may be made for members who meet the following criteria:

- Medical record documentation that Siklos is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of the age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of sickle cell anemia **AND**
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea

**NOTE:** Siklos can be dispersed in a small quantity of water in a teaspoon and administered immediately.

- Hydroxyurea is available as 500 mg capsules.
- Droxia (hydroxyurea) is available as 200 mg, 300 mg, 400 mg capsules.
- Siklos is available in 100 mg and 1,000 mg tablets. The 100 mg tablets can be split into 2 parts (50 mg each). The 1,000 mg tablets can be split into 4 parts (250 mg each).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved Siklos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY NUMBER: 601.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Siklos**

**FORMULARY ALTERNATIVES:**
hydroxyurea

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/17/20
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 602.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Xelpros** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xelpros for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xelpros may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan) within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to latanoprost

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Xelpros will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

latanoprost (generic Xalatan), travoprost

| Geisinger | POLICY NUMBER: 602.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xelpros |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 603.0**

**SECTION: Commercial Drug**
**SUBJECT: Tafluprost (generic Zioptan)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tafluprost (generic Zioptan) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of tafluprost (generic Zioptan) may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to latanoprost or Xelpros **AND** travoprost

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, tafluprost (generic Zioptan) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

latanoprost (generic Xalatan), travoprost, Xelpros*

*step therapy required

| Geisinger | POLICY NUMBER: 603.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tafluprost (generic Zioptan) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessica Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Travatan to generic, added ST indicator to Xelpros |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature; updated policy to generic tafluprost & added generic only approval language |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 604.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Sympazan**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sympazan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Sympazan may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Lennox-Gastaut syndrome **AND**
- Medical record documentation that Sympazan is being prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alternatives, one of which must be clobazam tablets or clobazam oral suspension

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 films per day

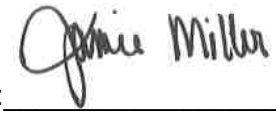
If an exception is made, Sympazan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
clobazam tablets, clobazam suspension, lamotrigine, topiramate, felbamate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/17/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 605.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Rinvoq** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rinvoq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***DMARD*** *– disease modifying anti-rheumatic drug*

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of rheumatoid arthritis**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Rinvoq is <u>not</u> being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of adalimumab* **OR** Enbrel*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*

*prior authorization required

**For treatment of psoriatic arthritis (PsA)**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of psoriatic arthritis **AND**
- Medical record documentation that Rinvoq is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Enbrel* **OR** adalimumab* **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

**For treatment of ankylosis spondylitis (AS)**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Enbrel* **OR** adalimumab* **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

**For treatment of atopic dermatitis (AD)**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation that Rinvoq is prescribed by an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
    - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable (use on sensitive areas, age between 2 and 15 years): Therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure to one systemic therapy (e.g., Dupixent, Adbry) **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation that Rinvoq will not be used in combination with another Janus kinase (JAK) inhibitor, biologic immunomodulator, or with other immunosuppressants including but not limited to azathioprine and cyclosporine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**

Dupixent*
Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*
Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)
Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

*prior authorization required

**For treatment of ulcerative colitis (UC)**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Rinvoq is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with adalimumab* **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** 45 mg once daily for 8 weeks

- In PA Hub: Add PA, OQL, number of claims authorized 2, max quantity dispensed 28 with a duration of 8 weeks
    - QL FOR LETTER: Loading dose: 56 tablets per 180 days; Maintenance dose: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

**For treatment of Crohn's disease**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation that Rinvoq is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that the medication is not being used in combination with a TNF blocker, other JAK inhibitor, biological therapy for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of adalimumab*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** 45 mg once daily for 12 weeks

- In PA Hub: Add PA, OQL, number of claims authorized 3, max quantity dispensed 28 with a duration of 12 weeks
    - QL FOR LETTER: Loading dose: 84 tablets per 180 days; Maintenance dose: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*

*prior authorization required

**For treatment of non-radiographic axial spondylarthritis (Nr-axSpA)**
An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of at least one of the following:
  - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
  - Sacroiliitis on magnetic resonance imaging (MRI) **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on one (1) preferred tumor necrosis factor (TNF) blocker **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

**FORMULARY ALTERNATIVES:**
Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Enbrel*

*prior authorization required

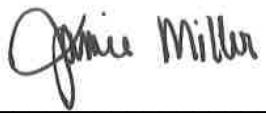
If an exception is made, Rinvoq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 605.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Rinvoq |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/27/20
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 6/7/22 – updated RA to GPI-14, added PsA, AS, AD, & UC indications
Revised: 10/6/22 – added combination use criterion for AD
Revised: 1/1/23 – updated to allow Rinvoq after Humira and/or Enbrel & FA for RA, PsA, AS, and UC
Revised: 1/19/23 – added Nr-axSpA indication
Revised: 3/1/23 – annual review; defined TNF; updated signature
Revised: 6/5/23 – updated Dupixent criterion to reflect a systemic therapy for AD
Revised: 11/1/23 – added CD indication; updated UC QL
Revised: 3/1/24 – annual review; updated criterion to adalimumab from Humira; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 606.0**

**SECTION: Commercial Drug**
**SUBJECT: Trikafta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trikafta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

A formulary exception for coverage of Trikafta may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that the medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis **AND**
- Medical record documentation of one of the following, as detected by a Food and Drug Administration (FDA) cleared cystic fibrosis mutation test:
    - Medical record documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene **OR**
    - Medical record documentation that the patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive based on in vitro data per product labeling

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - Tablets: 3 tablets per day, 28 day supply per fill
    - Oral Granules: 2 packets per day, 28 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms

of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

**NOTE:** List of CFTR mutations that is responsive to Trikafta

| | | | | | |
|---|---|---|---|---|---|
| *3141del9* | *E822K* | *G1069R* | *L967S* | *R117L* | *S912L* |
| *546insCTA* | *F191V* | *G1244E* | *L997F* | *R117P* | *S945L* |
| *A46D* | *F311del* | *G1249R* | *L1077P* | *R170H* | *S977F* |
| *A120T* | *F311L* | *G1349D* | *L1324P* | *R258G* | *S1159F* |
| *A234D* | *F508C* | *H139R* | *L1335P* | *R334L* | *S1159P* |
| *A349V* | *F508C;S1251N*† | *H199Y* | *L1480P* | *R334Q* | *S1251N* |
| *A455E* | *F508del** | *H939R* | *M152V* | *R347H* | *S1255P* |
| *A554E* | *F575Y* | *H1054D* | *M265R* | *R347L* | *T338I* |
| *A1006E* | *F1016S* | *H1085P* | *M952I* | *R347P* | *T1036N* |
| *A1067T* | *F1052V* | *H1085R* | *M952T* | *R352Q* | *T1053I* |
| *D110E* | *F1074L* | *H1375P* | *M1101K* | *R352W* | *V201M* |
| *D110H* | *F1099L* | *I148T* | *P5L* | *R553Q* | *V232D* |
| *D192G* | *G27R* | *I175V* | *P67L* | *R668C* | *V456A* |
| *D443Y* | *G85E* | *I336K* | *P205S* | *R751L* | *V456F* |
| *D443Y;G576A;R668C*† | *G126D* | *I502T* | *P574H* | *R792G* | *V562I* |
| *D579G* | *G178E* | *I601F* | *Q98R* | *R933G* | *V754M* |
| *D614G* | *G178R* | *I618T* | *Q237E* | *R1066H* | *V1153E* |
| *D836Y* | *G194R* | *I807M* | *Q237H* | *R1070Q* | *V1240G* |
| *D924N* | *G194V* | *I980K* | *Q359R* | *R1070W* | *V1293G* |
| *D979V* | *G314E* | *I1027T* | *Q1291R* | *R1162L* | *W361R* |
| *D1152H* | *G463V* | *I1139V* | *R31L* | *R1283M* | *W1098C* |
| *D1270N* | *G480C* | *I1269N* | *R74Q* | *R1283S* | *W1282R* |
| *E56K* | *G551D* | *I1366N* | *R74W* | *S13F* | *Y109N* |
| *E60K* | *G551S* | *K1060T* | *R74W;D1270N*† | *S341P* | *Y161D* |
| *E92K* | *G576A* | *L15P* | *R74W;V201M*† | *S364P* | *Y161S* |
| *E116K* | *G576A;R668C*† | *L165S* | *R74W;V201M;D1270N*† | *S492F* | *Y563N* |
| *E193K* | *G622D* | *L206W* | *R75Q* | *S549N* | *Y1014C* |
| *E403D* | *G628R* | *L320V* | *R117C* | *S549R* | *Y1032C* |
| *E474K* | *G970D* | *L346P* | *R117G* | *S589N* | |
| *E588V* | *G1061R* | *L453S* | *R117H* | *S737F* | |

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data *[see Clinical Studies (14)]*.
† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

If a formulary exception is approved Trikafta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 606.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Trikafta |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/28/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/24/21 – added CFTR mutations based on *in vitro* data, added chart to note |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 7/25/23 – updated age to 2 years; updated to GPI-10; added oral granule QL |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 608.0**

**SECTION: Commercial Drug**
**SUBJECT: Brukinsa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Brukinsa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Brukinsa may be made for members who meet the following criteria:

**Mantle Cell Lymphoma**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of mantle cell lymphoma **AND**
- Medical record documentation of therapeutic failure on or intolerance to one prior therapy

**Waldenström's macroglobulinemia**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of Waldenström's macroglobulinemia

**Marginal Zone Lymphoma (MZL)**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) **AND**
- Medical record documentation of therapeutic failure on or intolerance to one prior anti-CD20-based regimen

**Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

If a formulary exception is approved, Brukinsa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Mantle Cell Lymphoma: Imbruvica*, Revlimid*, Calquence*

*prior authorization required

| Geisinger | POLICY NUMBER: 608.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Brukinsa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/28/20 |
| Revised: | 3/1/20 – annual review, added GHP Kids |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature; added Waldenström's, MZL, CLL/SLL indications |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 609.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Enstilar and Wynzora**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Enstilar and Wynzora for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Enstilar or Wynzora may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years if request is for Enstilar **OR** age greater than or equal to 18 years if request is for Wynzora **AND**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to a combination of a topical vitamin D analog and a topical corticosteroid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Enstilar or Wynzora will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

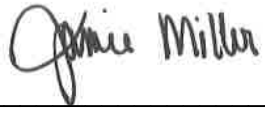
**Vitamin D Analogs:** calcipotriene 0.005% cream/ointment*, calcitriol 3 mcg/g ointment*
**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and

solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

*off-label for under 18 years of age

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 7/20/22 – updated topical corticosteroid alternatives

Revised: 12/8/22 – added Wynzora to policy with age criteria
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 610.0**

**SECTION: Commercial Drug**
**SUBJECT: Vascepa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vascepa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vascepa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of severe hypertriglyceridemia (triglycerides greater than or equal to 500 mg/dL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to omega-3 acid ethyl esters (generic Lovaza)

**OR**

- Medical record documentation of established cardiovascular disease (documented history of coronary heart disease, cerebrovascular or carotid disease, or peripheral arterial disease) **OR** documentation of a diagnosis of diabetes mellitus and at least **TWO** cardiovascular additional risk factors* **AND**
- Medical record documentation of use in combination with, or an intolerance to, or contraindication to moderate- or high-intensity statin therapy **AND**
- Medical record documentation of a baseline (pre-initiation of Vascepa) triglyceride level greater than or equal to 150 mg/dL

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Vascepa 0.5 grams: 8 capsules per day
  - Vascepa 1 gram: 4 capsules per day

***NOTE:** Cardiovascular Risk Factors

- Age (men ≥55; women ≥65 years of age);
- Cigarette smoker or stopped smoking within 3 months;
- Hypertension (BP ≥140 mmHg systolic OR ≥90 mmHg diastolic) or on antihypertensive medication;
- HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women;
- High sensitivity C-Reactive Protein >3.00 mg/L (0.3 mg/dL);
- CrCL >30 and <60 mL/min;
- Retinopathy;
- Micro- or macroalbuminuria;
- ABI <0.9 without symptoms of intermittent claudication

If a formulary exception is approved Vascepa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin, omega-3 acid ethyl esters

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/29/20
Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 611.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ayvakit**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ayvakit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Ayvakit may be made for members who meet the following criteria:

**Gastrointestinal Stromal Tumor (GIST)**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ayvakit is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of unresectable or metastatic gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation

**Advanced Systemic Mastocytosis (AdvSM)**

- Medical record documentation that Ayvakit is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a platelet count greater than or equal to 50 x $10^9$/L **AND**
- Medical record documentation of a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

**Indolent Systemic Mastocytosis (ISM)**

- Medical record documentation that Ayvakit is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a platelet count greater than or equal to 50 x $10^9$/L **AND**
- Medical record documentation of indolent systemic Mastocytosis (ISM) **AND**
- Medical record documentation of a dose consistent with Food and Drug Administration (FDA) approved labeling

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 for GSIT and AdvSM, GPI-14 for ISM, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Ayvakit is configured as a prior authorization for new starts only. Ayvakit will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Ayvakit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

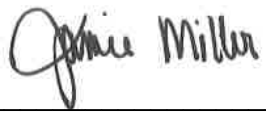
GIST: imatinib*, Sprycel*, Stivarga*, sunitinib*

*prior authorization required

| Geisinger | POLICY NUMBER: 611.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ayvakit |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/9/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 9/1/21 – added AdvSM indication |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 11/1/23 – added ISM indication |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 612.0**

**SECTION: Commercial Drug**
**SUBJECT: Wakix**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Wakix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Wakix may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Diagnosis of narcolepsy with cataplexy **OR**
  - Diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil or armodafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

**AUTHORIZATION DURATION:**

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in symptoms of excessive daytime sleepiness **OR**
- Medical record documentation of reduction in frequency of cataplexy attacks

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness **OR**

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks

If a formulary exception is approved Wakix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

armodafinil*, modafinil*, dextroamphetamine/amphetamine immediate release methylphenidate immediate release

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/9/20
Revised: 11/18/20 – added authorization duration
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added narcolepsy with cataplexy indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 613.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tazverik**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tazverik for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tazverik may be made for members who meet the following criteria:

**Advanced Epithelioid Sarcoma**

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation that Tazverik is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of metastatic or locally advanced epithelioid sarcoma **AND**
- Medical record documentation that member is not eligible for complete resection

**Relapsed or Refractory Follicular Lymphoma**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tazverik is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory follicular lymphoma **AND**
- Medical record documentation of one of the following:
    - Documentation of an EZH2 mutation as detected by a Food and Drug Administration (FDA) approved test **AND** documentation that member has received at least two (2) prior systemic therapies **OR**
    - Documentation of no satisfactory alternative treatment options

***NOTE:** The FDA-approved test for the detection of EZH2 mutation in relapsed or refractory lymphoma is the cobas EZH2 Mutation Test. The cobas® EZH2 Mutation Test is a real-time allele-specific PCR test for qualitative detection of single nucleotide mutations for Y646N, Y646F or Y646X (Y646H, Y646S, or Y646C), A682G, and A692V of the EZH2 gene.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Tazverik is configured as a prior authorization for new starts only. Tazverik will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tazverik will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

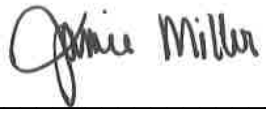
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 613.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Tazverik** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/21/20 |
| Revised: | 10/12/20 – added follicular lymphoma indication and note |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 8/2/22 – corrected typo in EZH2 mutation |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 614.0**

**SECTION: Commercial Drug**
**SUBJECT: Nourianz**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nourianz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nourianz may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Nourianz is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of Parkinson's disease with "OFF" episodes or motor fluctuations **AND**
- Medical record documentation that Nourianz will be used as adjunctive treatment to carbidopa/levodopa **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Nourianz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 614.0**

**SECTION: Commercial Drug**
**SUBJECT: Nourianz**

**FORMULARY ALTERNATIVES:**
carbidopa/levodopa/entacapone, entacapone, pramipexole, rasagiline, ropinirole, selegiline

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/21/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 615.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Tolcapone**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tolcapone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of tolcapone may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Ongentys **AND** entacapone or carbidopa/levodopa/entacapone within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Ongentys **AND** entacapone or carbidopa/levodopa/entacapone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved, tolcapone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

carbidopa/levodopa/entacapone, entacapone, pramipexole, pramipexole extended release*, rasagiline, ropinirole, selegiline, apomorphine*, Inbrija, Ongentys*

*prior authorization or step therapy required

| Geisinger | POLICY NUMBER: 615.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tolcapone |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/21/20
Revised: 1/22/21 – Added failure of Ongentys to ST, updated FA, added MediSpan approval level
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY NUMBER: 616.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Pretomanid**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pretomanid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Pretomanid may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Pretomanid is prescribed by a physician specializing in infectious disease **AND**
- Medical record documentation of pulmonary infection due to *Mycobacterium tuberculosis* **AND**
- Medical record documentation of one of the following:
  - Extensively drug resistant tuberculosis (XDR-TB) **OR**
  - Treatment-intolerant or nonresponsive multidrug-resistant tuberculosis (TI/NR MDR-TB) **AND**
- Medical record documentation that Pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

**AUTHORIZATION DURATION:** 26 weeks

**NOTE:**

- TI/NR MDR-TB organisms are resistant to rifampin and isoniazid and possibly additional agents.

- XDR-TB organisms are resistant to isoniazid, rifampin, a fluroquinolone, and a second-line injectable (amikacin, capreomycin, and kanamycin) **OR** are resistant to isoniazid, rifampin, a fluroquinolone, and bedaquiline or linezolid.

If a formulary exception is approved, Pretomanid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

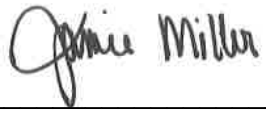
**FORMULARY ALTERNATIVES:**

moxifloxacin, levofloxacin, linezolid tablets, linezolid suspension*, ethambutol, pyrazinamide, Sirturo*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/21/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 10/3/22 – updated XDR-TB definition
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 617.0**

**SECTION: Commercial Drug**
**SUBJECT: Valtoco**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Valtoco for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Valtoco may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **OR**
- Medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature **AND**
- For patients are least 2 years of age: medical record documentation of why diazepam rectal gel cannot be used

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12 (must include 7210003000C4 & 721000300009)

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 nasal spray units per 30 days

If a formulary exception is approved, Valtoco will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 617.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Valtoco |

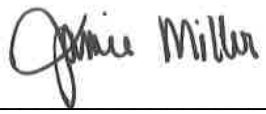
**FORMULARY ALTERNATIVES:**

diazepam rectal gel, Nayzilam^, Diastat AcuDial

^quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 4/21/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 10/6/22 – updated age indication to an OR statement |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 618.0**

**SECTION: Commercial Drug**
**SUBJECT: Caplyta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Caplyta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Caplyta may be made for members who meet the following criteria:

**Schizophrenia**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary atypical antipsychotics **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ziprasidone **AND** aripiprazole for members with metabolic syndrome

**Bipolar Depression**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

If a formulary exception is approved, Caplyta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Schizophrenia: aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone

Bipolar Depression: quetiapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/21/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added bipolar depression
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 619.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Abilify Mycite**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Abilify Mycite for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Abilify Mycite may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Diagnosis of schizophrenia **OR**
  - Diagnosis of use for acute treatment of manic and mixed episodes or maintenance treatment of Bipolar I disorder as monotherapy or as adjunct to lithium or valproate **OR**
  - Diagnosis of use as adjunctive treatment of major depressive disorder

**AND**

- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of access to a compatible smart phone **AND**
- Medical record documentation of one of the following:
  - For schizophrenia and bipolar I disorder:
    - Medical record documentation of reason why aripiprazole oral tablets **AND** Abilify Maintena cannot be used

  **OR**

  - For major depressive disorder (MDD)
    - Medical record documentation of reason why aripiprazole oral tablets cannot be used

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

**AUTHORIZATION DURATION:** Initial authorizations for Abilify Mycite will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Claims history and attestation from the provider showing the patient is adherent to Abilify Mycite **OR** continued need to monitor drug ingestion **AND**
- Medical record documentation of one of the following:
  - For schizophrenia and bipolar I disorder:
    - Medical record documentation or reason why aripiprazole oral tablets **AND** Abilify Maintena cannot be used **OR**
  - For major depressive disorder (MDD):
    - Medical record documentation of reason why aripiprazole oral tablets cannot be used

If a formulary exception is approved, Abilify Mycite will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

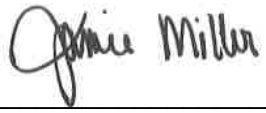
**FORMULARY ALTERNATIVES:**

aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 619.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Abilify Mycite** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/29/20 |
| Revised: | 7/29/20 – added alternative criteria to reauthorization |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 620.0**

**SECTION: Commercial Drug**
**SUBJECT: Consensi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Consensi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Consensi may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure or intolerance to an adequate trial of three (3) combinations of formulary NSAID **AND** calcium-channel blocker therapies, one of which must be amlodipine and celecoxib used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Consensi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 620.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Consensi** |

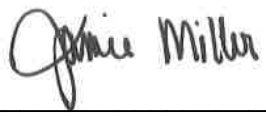
**FORMULARY ALTERNATIVES:**

Calcium-Channel Blockers: amlodipine, felodipine extended release, nifedipine extended release

NSAIDs: celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/29/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 621.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Koselugo |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Koselugo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Koselugo may be made for members who meet the following criteria:

- Medical record documentation that Koselugo is prescribed by or in consultation with at least one of the following:
  - Pediatric oncologist
  - Pediatric neurologist
  - Pediatric geneticist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of neurofibromatosis type 1 as defined by a positive *NF1* mutation **OR** two of the following:
  - Diagnosis of schizophrenia **OR**
  - Six or more brown oval/circular spots on the skin called café-au-lait macules (> 5 mm diameter in prepubertal individuals and > 15 mm in post-pubertal individuals)
  - Freckling in axillary or inguinal regions
  - Two or more neurofibromas of any type, or one plexiform neurofibroma
  - A tumor of the nerve to the eye called optic glioma
  - Two or more Lisch nodules (iris hamartomas)
  - A distinctive osseous lesion (sphenoid dysplasia or tibial pseudarthrosis)
  - A first degree relative with NF1

**AND**

- Medical record documentation of symptomatic, inoperable* plexiform neurofibromas (PN)

***NOTE:** In clinical trials, inoperable PN was defined as a PN that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 10 mg capsules: 8 capsules per day, 30 day supply per fill
  - 25 mg capsules: 4 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Koselugo is configured as a prior authorization for new starts only. Koselugo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Koselugo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

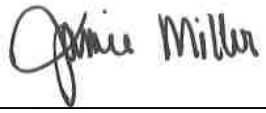
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 621.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Koselugo** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2023

Devised: 5/29/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 622.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Oxbryta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oxbryta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Oxbryta may be made for members who meet the following criteria:

- Medical record documentation that Oxbryta is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of sickle cell disease **AND**
- Medical record documentation of baseline hemoglobin **AND**
- Medical record documentation of one of the following:
    - For members 5 years of age and older: medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum three (3) month trial of generic hydroxyurea **AND** Endari
    - For members less than 5 years of age: medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum three (3) month trial of generic hydroxyurea **AND**
- If the requested quantity exceeds three tablets per day of Oxbryta 500 mg or five tablets per day of Oxbryta 300 mg: Medical record documentation that the patient is using Oxbryta in combination with a strong or moderate CYP3A4 inducer, including but not limited to apalutamide, bosentan, carbamazepine, efavirenz, etravirine, enzalutamide, mitotane, phenobarbital, phenytoin, primidone, rifampin, St. John's Wort

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is recommended for reauthorization:

- Medical record documentation of an increase in hemoglobin from baseline or an improvement in complications of sickle cell disease (e.g., decrease in vaso-occlusive crisis related emergencies) **AND**
- If the requested quantity exceeds three tablets per day of Oxbryta 500 mg or five tablets per day of Oxbryta 300 mg: Medical record documentation that the patient is using Oxbryta in combination with a strong or moderate CYP3A4 inducer, including but not limited to apalutamide, bosentan, carbamazepine, efavirenz, etravirine, enzalutamide, mitotane, phenobarbital, phenytoin, primidone, rifampin, St. John's Wort

If a formulary exception is approved, Oxbryta will be paid for under the member's prescription drug benefit.

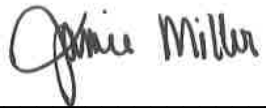
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
hydroxyurea, Endari*, Siklos*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Geisinger

**POLICY NUMBER: 622.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Oxbryta**

Date: March 1, 2024

| | |
|---|---|
| Devised: | 5/29/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo |
| Revised: | 6/7/22 – updated age to 4 years, updated FA criterion to separate ages, updated QL criterion |
| Revised: | 3/1/23 – annual review; updated signature; corrected typo in QL criterion |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 623.0**

**SECTION: Commercial Drug**
**SUBJECT: Oxervate**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oxervate for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Oxervate may be made for members who meet the following criteria:

- Medical record documentation that Oxervate is prescribed by an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of neurotrophic keratitis (MK) as confirmed by a decrease or loss in corneal sensitivity **AND** one of the following:
    - Superficial keratopathy
    - Persistent epithelial defects
    - Corneal ulcers

**AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional non-surgical treatment for neurotrophic keratitis (NK) (e.g., preservative-free artificial tears, gels/ointments; discontinuation of preserved topical drops and medications that can decrease corneal sensitivity; therapeutic contact lenses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cyclosporine (generic Restasis) **OR** Xiidra

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 56 vials per 28 days

**AUTHORIZATION DURATION:** 8 weeks

For requests beyond the FDA-approved treatment duration (8 weeks), documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration is required.

If a formulary exception is approved, Oxervate will be paid for under the member's prescription drug benefit.

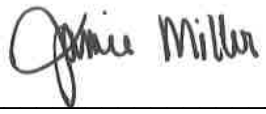
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

cyclosporine ophthalmic suspension (generic Restasis), Xiidra

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/29/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Revised: 3/1/23 – annual review; added generic name for Restasis; updated signature
Revised: 3/1/24 – annual review; updated Restasis to generic only; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 624.0**

**SECTION: Commercial Drug**
**SUBJECT: Secuado**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Secuado for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Secuado may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to asenapine (Saphris) **AND** two additional formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 patch per day

If a formulary exception is approved, Secuado will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 624.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Secuado |

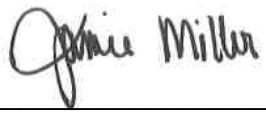
**FORMULARY ALTERNATIVES:**

asenapine*, aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/4/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 625.0**

**SECTION: Commercial Drug**
**SUBJECT: Talicia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Talicia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Talicia may be made for members who meet the following criteria:

- Medical record documentation of confirmed *Helicobacter pylori* infection **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy for *H. pylori* infection **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amoxicillin **AND** rifabutin **AND** a formulary proton pump inhibitor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 168 tablets per 14 days

If a formulary exception is approved, Talicia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

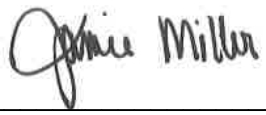
**FORMULARY ALTERNATIVES:**

amoxicillin, rifabutin, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole

| Geisinger | **POLICY NUMBER: 625.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Talicia** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/4/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 626.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ubrelvy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ubrelvy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ubrelvy may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ubrelvy will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary triptans **AND**
- Medical record documentation that Ubrelvy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g., Nurtec ODT)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 16 tablets per 30 days

If a formulary exception is approved, Ubrelvy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 626.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ubrelvy |

**FORMULARY ALTERNATIVES:**

dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan*^, eletriptan*^, frovatriptan*^, naratriptan^, rizatriptan^, sumatriptan^, zolmitriptan^, sumatriptan/naproxen*^

*prior authorization required, ^quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/4/20 |
| Revised: | 7/28/20 – added concomitant CGRP criterion |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/19/21 – removed failure of NSAID, changed triptans from 3 to 2 |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 627.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Pemazyre**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pemazyre for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Pemazyre may be made for members who meet the following criteria:

**Cholangiocarcinoma**

- Medical record documentation that Pemazyre is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of a fibroblast growth factor receptor 2 (FGFR2) fusions or other rearrangement as verified by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of one prior line of therapy

**NOTE:** The FDA approved test for cholangiocarcinoma is the FoundationOne CDx.

**Myeloid/Lymphoid Neoplasms**

- Medical record documentation that Pemazyre is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of relapsed or refractory myeloid/lymphoid neoplasms (MLNS) **AND**

- Medical record documentation of a fibroblast growth factor receptor 1 (FGFR1) rearrangement

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

**RE-AUTHORIZATION CRITERIA:** Pemazyre is configured as a prior authorization for new starts only. Pemazyre will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Pemazyre will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

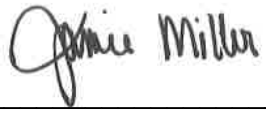
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 627.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Pemazyre** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 9/1/21 – corrected typo from P&T by adding unresectable to diagnosis criterion |
| Revised: | 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/7/22 – added MLNS indication, updated QL |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 628.0**

**SECTION: Commercial Drug**
**SUBJECT: Xcopri**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xcopri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xcopri may be made for members who meet the following criteria:

- Medical record documentation that Xcopri is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of partial onset seizures **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg, 100 mg, 150 mg: 1 tablet per day
  - Maintenance Pack, 200 mg: 2 tablets per day
  - Titration Pack: 28 tablets per 180 days

If a formulary exception is approved, Xcopri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

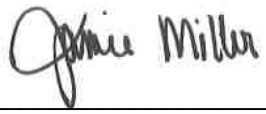
**FORMULARY ALTERNATIVES:**

carbamazepine, divalproex, felbamate, gabapentin, tiagabine, lamotrigine IR, lamotrigine ER, levetiracetam IR, levetiracetam ER, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER*, zonisamide

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 629.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nurtec ODT**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nurtec ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nurtec ODT may be made for members who meet the following criteria:

**Acute Migraine Treatment**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Nurtec ODT will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary triptans **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g., Ubrelvy)

**Preventive Migraine Treatment**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of diagnosis of episodic migraine (no more than 14 headache days per month) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
  - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
  - Topiramate
  - Divalproex/sodium valproate
  - Amitriptyline
  - Venlafaxine **AND**

- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment **OR**
    - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**AUTHORIZATION DURATION FOR PREVENTIVE TREATMENT:** Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment **OR**
    - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 18 tablets per 30 days

**ICHD-III Diagnostic Criteria** [3]

| **Migraine without Aura:** | **Migraine with Aura:** |
|---|---|
| A) At least five (5) attacks fulfilling criteria B through D below: | A) At least two (2) attacks fulfilling criteria B through C below: |
| B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated) | B) One (1) or more of the following fully reversible aura symptoms:<br>o Visual<br>o Sensory<br>o Speech and/or language<br>o Motor<br>o Brainstem<br>o Retinal |
| C) Headache with at least two (2) of the following characteristics:<br>o unilateral location<br>o pulsating quality<br>o moderate to severe pain intensity<br>o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) | C) At least three (3) of the following:<br>o at least one (1) aura symptom spreads over 5 or more minutes<br>o two (2) or more aura symptoms occur in succession<br>o each individual aura symptom lasts 5 to 60 minutes[1]<br>o at least one (1) aura symptom is unilateral[2]<br>o at least one (1) aura symptom is positive[3]<br>o the aura is accompanied, or followed within 60 minutes, by a headache |
| D) At least one of the following during the headache:<br>o nausea and/or vomiting<br>o photophobia and phonophobia | D) Not better accounted for by another ICHD-3 diagnosis |
| E) Not better accounted for by another ICHD-3 diagnosis | |

If a formulary exception is approved, Nurtec ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

**Acute Treatment:** dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan*^, eletriptan*^, frovatriptan*^, naratriptan^, rizatriptan^, sumatriptan^, zolmitriptan^, sumatriptan/naproxen*^

**Preventive Treatment:** metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Aimovig*, Emgality*

*prior authorization required, ^quantity limits apply

| Geisinger | POLICY NUMBER: 629.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Nurtec ODT |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/19/21 – acute indication: removed failure of NSAID, changes from 3 to 2 triptans, added preventive indication, updated QL to 18 tablets, updated FA, added ICHD tablet |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 1/20/23 – for migraine: updated to failure of 2 generic alts; removed failure of alt CGRP's; removed prescriber requirement; removed diag based on ICHD 3 criteria; removed CGRF examples from concomitant use criteria; updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 630.0**

**SECTION: Commercial Drug**
**SUBJECT: Palforzia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Palforzia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Palforzia may be made for members who meet the following criteria:

- Medical record documentation that Palforzia is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- If the request is for initial dose escalation: Medical record documentation that member is greater than or equal to 4 years of age to less than 18 years of age **OR**
- If the request is for up-dosing or maintenance dose: Medical record documentation that member is greater than or equal to 4 years of age

**AND**

- Medical record documentation of confirmed diagnosis of peanut-allergy with history of allergic reaction from peanuts **AND** one of the following:
  - positive skin test **OR**
  - *in vitro* testing for peanut-specific IgE antibodies

**AND**

- Medical record documentation that Palforzia will be used in conjunction with peanut-avoidant diet **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that the member has no experienced severe or life-threatening anaphylaxis within 60 days of Palforzia initiation

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:

| Packaging Presentation | Quantity Limits |
|---|---|
| **Initial Dose Escalation** | |
| 0.5 mg to 6 mg capsules | 13 capsules / 1 day |
| **Up-Dosing** | |
| 3 mg (Level 1) | 3 capsules / day, 30 day supply per fill |
| 6 mg (Level 2) | 6 capsules / day, 30 day supply per fill |
| 12 mg (Level 3) | 3 capsules / day, 30 day supply per fill |
| 20 mg (Level 4) | 1 capsule / day, 30 day supply per fill |
| 40 mg (Level 5) | 2 capsules / day, 30 day supply per fill |
| 80 mg (Level 6) | 4 capsules / day, 30 day supply per fill |
| 120 mg (Level 7) | 2 capsules / day, 30 day supply per fill |
| 160 mg (Level 8) | 4 capsules / day, 30 day supply per fill |
| 200 mg (Level 9) | 2 capsules / day, 30 day supply per fill |
| 240 mg (Level 10) | 4 capsules / day, 30 day supply per fill |
| 300 mg (Level 11) | 1 packet / day, 30 day supply per fill |
| Maintenance | |
| 300 mg (Level 11) | 1 packet / day, 30 day supply per fill |

**AUTHORIZATION DURATION:** Initial authorizations for Palforzia will be approved for a period of 12 months. Subsequent authorizations will be for a period of 12 months and will require the following criteria:

- Claims history and attestation from the provider showing the patient is adherent to daily dosing of Palforzia **AND**.
- Medical record documentation that patient is not experiencing unacceptable toxicity **AND**
- Medical record documentation that patient does not have recurrent asthma exacerbations or persistent loss of asthma control **AND**
- Medical record documentation that patient does not have suspected eosinophilic esophagitis

If a formulary exception is approved, Palforzia will be paid for under the member's prescription drug benefit.

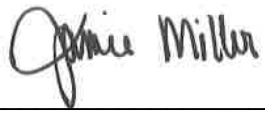
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 630.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Palforzia |

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 10/13/20 – removed Pemazyre criteria |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 631.0**

**SECTION: Commercial Drug**
**SUBJECT: Qinlock**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qinlock for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Qinlock may be made for members who meet the following criteria:

- Medical record documentation that Qinlock is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of prior treatment with three (3) or more kinase inhibitors, including imatinib

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 90 tablets per 30 days

**RE-AUTHORIZATION CRITERIA:** Qinlock is configured as a prior authorization for new starts only. Qinlock will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Qinlock will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

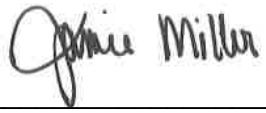
**FORMULARY ALTERNATIVES:**

imatinib*, sunitinib*, Stivarga*, Ayvakit*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 632.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Retevmo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Retevmo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Retevmo may be made for members who meet the following criteria:

**Non-Small Cell Lung Cancer**

- Medical record documentation that Retevmo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of *RET*-fusion positive non-small cell lung cancer (NSCLC)

**Thyroid Cancer**

- Medical record documentation that Retevmo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of advanced metastatic *RET*-mutant medullary thyroid cancer (MTC) **AND** medical record documentation that systemic therapy is required

**OR**

- Medical record documentation of advanced or metastatic *RET* fusion-positive thyroid cancer **AND** medical record documentation of both of the following:
  - Documentation that systemic therapy is required **AND**
  - Documentation that member is radioactive-iodine refractory when radioactive iodine is appropriate

**Solid Tumors**

- Medical record documentation that Retevmo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a locally advanced or metastatic solid tumors with a RET gene fusion **AND**
- Medical record documentation of progression on or following prior systemic therapy **OR**
- Medical record documentation that patient has no satisfactory alternative treatment options

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 40 mg capsules: 2 capsules per day, 30 day supply per fill
  - 80 mg capsules: 4 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Retevmo is configured as a prior authorization for new starts only. Retevmo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Retevmo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

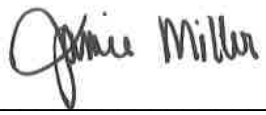
**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 632.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Retevmo |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/7/22 – added solid tumor indication |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 633.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Reyvow** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Reyvow for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Reyvow may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Reyvow will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to nonsteroidal anti-inflammatory drug (NSAID) therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary triptans **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Ubrelvy **AND** Nurtec ODT for acute treatment

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg: 4 tablets per 30 days
  - 100 mg: 8 tablets per 30 days

If a formulary exception is approved, Reyvow will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 633.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Reyvow |

**FORMULARY ALTERNATIVES:**

dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan*^, eletriptan*^, frovatriptan*^, naratriptan^, rizatriptan^, sumatriptan^, zolmitriptan^, sumatriptan/naproxen*^, Ubrelvy*^, Nurtec ODT*^

*prior authorization required, ^quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/19/21 – added failure of Ubrelvy and Nurtec |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 634.0**

**SECTION: Commercial Drug**
**SUBJECT: Tabrecta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tabrecta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tabrecta may be made for members who meet the following criteria:

- Medical record documentation that Tabrecta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Tabrecta is configured as a prior authorization for new starts only. Tabrecta will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tabrecta will be paid for under the member's prescription drug benefit.

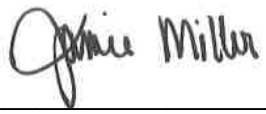
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 635.0**

**SECTION: Commercial Drug**
**SUBJECT: Tukysa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tukysa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tukysa may be made for members who meet the following criteria:

**HER2-Positive Breast Cancer**

- Medical record documentation that Tukysa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases **AND**
- Medical record documentation that Tukysa will be given in combination with trastuzumab and capecitabine **AND**
- Medical record documentation of prior treatment with at least one anti-HER2 based regimen in the metastatic setting

**RAS Wild Type, HER2-Positive Metastatic Colorectal Cancer**

- Medical record documentation that prescription is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of RAS wild-type HER2-positive unresectable or metastatic colorectal cancer **AND**
- Medical record documentation that Tukysa will be given in combination with trastuzumab **AND**
- Medical record documentation of prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Tukysa is configured as a prior authorization for new starts only. Tukysa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tukysa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 635.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tukysa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/28/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature; added colorectal CA indication |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 636.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Dayvigo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dayvigo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Dayvigo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of insomnia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Dayvigo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

zolpidem immediate release, zolpidem extended release, eszopiclone, zaleplon, quazepam, estazolam, flurazepam, triazolam, temazepam, doxepin (generic Silenor), zolpidem sublingual*, ramelteon*

*prior authorization or step therapy required

Geisinger

**POLICY NUMBER: 636.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Dayvigo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/5/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, corrected typo |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 637.0**

**SECTION: Commercial Drug**
**SUBJECT: Fintepla**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fintepla for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fintepla may be made for members who meet the following criteria:

- Medical record documentation that Fintepla is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of one of the following:
  - Dravet syndrome **OR**
  - Lennox-Gastaut syndrome **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives appropriate for diagnosis

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 12 mL per day

If a formulary exception is approved, Fintepla will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 637.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Fintepla |

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Dravet syndrome:
For patients > 2 years of age: clobazam, Diacomit*, Epidiolex*, topiramate IR, topiramate ER (generic Qudexy XR)*

Additional formulary alternatives for patients over certain ages: levetiracetam IR (4+), divalproex (10+), valproic acid (10+), levetiracetam ER (12+)

Lennox-Gastaut syndrome:
For patients > 2 years of age: clobazam, clonazepam, Epidiolex*, felbamate, lamotrigine IR, rufinamide*, Sympazan*, topiramate IR, topiramate ER (generic Qudexy XR)*

Additional formulary alternatives for patients over certain ages: lamotrigine ER (13+),

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 10/5/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 6/7/22 – added Lennox-Gastaut, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 638.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Isturisa |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Isturisa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Isturisa may be made for members who meet the following criteria:

- Medical record documentation that Isturisa is prescribed by an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, metopirone, Signifor, Signifor LAR

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 1 mg tablets: 8 tablets per day, 30 day supply per fill
  - 5 mg tablets: 2 tablets per day, 30 day supply per fill
  - 10 mg tablets: 6 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.

If a formulary exception is approved, Isturisa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

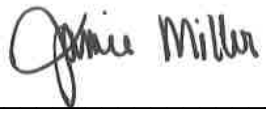
**FORMULARY ALTERNATIVES:**

ketoconazole, cabergoline, Lysodren, Signifor*, Korlym*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/5/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 639.0**

**SECTION: Commercial Drug**
**SUBJECT: Kristalose Packets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kristalose packets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Kristalose packets may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lactulose liquid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If a formulary exception is approved, Kristalose packets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

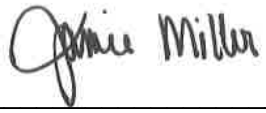
**FORMULARY ALTERNATIVES:**

lactulose liquid

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 639.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Kristalose Packets** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/12/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 640.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nexletol**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nexletol for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nexletol may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **AND**
- Medical record documentation that Nexletol is prescribed by a cardiologist or lipidologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of Nexletol therapy with one of the following:
  - Low-density lipoprotein (LDL) greater than 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and is using Nexletol for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or either heterozygous familial hypercholesterolemia (HeFH) and is using Nexletol for secondary prevention **AND**

- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Nexletol will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

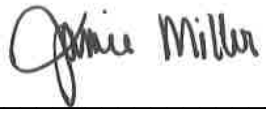
**FORMULARY ALTERNATIVES:**

atorvastatin, rosuvastatin, ezetimibe, cholestyramine, colestipol, fenofibrate, fluvastatin, gemfibrozil, lovastatin, pravastatin, simvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 640.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Nexletol** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/17/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – updated ESC/EAS to Dutch Lipid
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 641.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Nexlizet**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nexlizet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Nexlizet may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **AND**
- Medical record documentation that Nexlizet is prescribed by a cardiologist or lipidologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of Nexlizet therapy with one of the following:
  - Low-density lipoprotein (LDL) greater than 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and is using Nexlizet for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or either heterozygous familial hypercholesterolemia (HeFH) and is using Nexlizet for secondary prevention **AND**

- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe alone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Nexlizet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

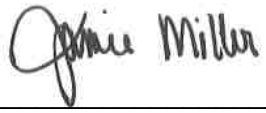
**FORMULARY ALTERNATIVES:**

atorvastatin, rosuvastatin, ezetimibe, cholestyramine, colestipol, fenofibrate, fluvastatin, gemfibrozil, lovastatin, pravastatin, simvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 641.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Nexlizet** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/17/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – updated ESC/EAS to Dutch Lipid
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 642.0**

**SECTION: Commercial Drug**
**SUBJECT: Santyl**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Santyl for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Santyl may be made for members who meet the following criteria:

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds **AND**
- Medical record documentation of the wound length and width **AND**
- Medical record documentation of anticipated duration of therapy **AND**
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*

***NOTE:** Please calculate the dose on the manufacturer's website to confirm it is within a medically appropriate range - https://santyl.com/hcp/dosing

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 3 months. Subsequent approval will be for 3 months. Reauthorization will require:

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds **AND**
- Medical record documentation of the wound length and width **AND**
- Medical record documentation of anticipated duration of therapy **AND**
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*

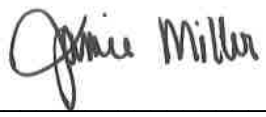
If a formulary exception is approved, Santyl will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/18/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 8/24/21 – updated reauthorization criteria |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 643.0**

**SECTION: Commercial Drug**
**SUBJECT: Inqovi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inqovi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Inqovi may be made for members who meet the following criteria:

- Medical record documentation that Inqovi is prescribed by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 5 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Inqovi is configured as a prior authorization for new starts only. Inqovi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Inqovi will be paid for under the member's prescription drug benefit.

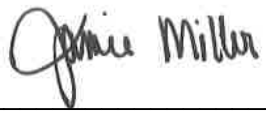
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/17/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 644.0**

**SECTION: Commercial Drug**
**SUBJECT: Dojolvi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dojolvi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Dojolvi may be made for members who meet the following criteria:

- Medical record documentation that Dojolvi is prescribed by or in consultation with a metabolic specialist or a physician who specialized in the management of long-chain fatty acid oxidation disorders **AND**
- Medical record documentation of a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD) confirmed by at least two of the following:
    - Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
    - Low enzyme activity in cultured fibroblasts
    - One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g. *CPT2, ACADVL, HADHA,* or *HADHB)* **AND**
- Medical record documentation that the member is currently managed on a treatment regimen which may include a low-fat, high carbohydrate diet; avoidance or fasting; and/or medium-chain triglyceride (MCT) oil

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement* or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

***NOTE:** Signs of improvement for a patient with LC-FAOD can include any of the following, but are not limited to: gross motor development/motor function for infants and young children, exercise tolerance and endurance for older children and adults, and a decrease in the frequency of major medical episodes of hypoglycemia, rhabdomyolysis, and exacerbation of cardiomyopathy.

If a formulary exception is approved, Dojolvi will be paid for under the member's prescription drug benefit.

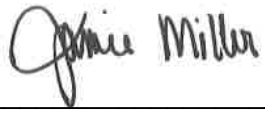
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/18/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 7/25/23 – corrected typo |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 645.0**

**SECTION: Commercial Drug**
**SUBJECT: Gavreto**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gavreto for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Gavreto may be made for members who meet the following criteria:

**Non-Small Cell Lung Cancer**

- Medical record documentation that Gavreto is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a rearranged during transfection (RET) – fusion positive tumor as detected by a Food and Drug Administration (FDA) approved test*

**Thyroid Cancer**

- Medical record documentation that Gavreto is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) **AND** documentation that systemic therapy is required **OR**
  - Medical record documentation of advanced or metastatic RET fusion-positive thyroid cancer **AND** medical record documentation of both of the following:

- Documentation that systemic therapy is required **AND**
- Documentation that patient is radioactive-iodine refractory when radioactive iodine is appropriate

***NOTE:** The FDA approved companion diagnostic test for Gavreto to determine the presence of a RET gene fusion is the Oncomine Dx Target Test.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Gavreto is configured as a prior authorization for new starts only. Gavreto will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Gavreto will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

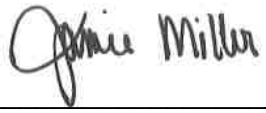
Caprelsa*, Cometriq*, Retevmo*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 645.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Gavreto** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/18/20 |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 3/26/21 – added thyroid cancer indication |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 646.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Onureg**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Onureg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Onureg may be made for members who meet the following criteria:

- Medical record documentation that Onureg is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of acute myeloid leukemia **AND**
- Medical record documentation the member achieved first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy **AND**
- Medical record documentation that member is not able to complete intensive curative therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 14 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Onureg is configured as a prior authorization for new starts only. Onureg will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Onureg will be paid for under the member's prescription drug benefit.

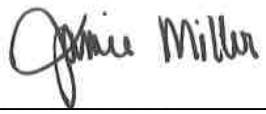
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 11/18/20 |
| Revised: | 1/21/21 – corrected Gavreto typo |
| Revised: | 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement |
| Revised: | 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 647.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Evrysdi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Evrysdi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Evrysdi may be made for members who meet the following criteria:

- Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of one of the following:
    - A confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
        - Homozygous exon 7 gene deletion **OR**
        - Homozygous exon 7 conversion mutation **OR**
        - Compound heterozygous exon 7 mutation **OR**
    - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

  **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g., Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g., Spinraza)

***NOTE:** Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 240 mL per 36 days

**AUTHORIZATION DURATION:** Evrysdi will be approved for an initial authorization duration of 12 months. Subsequent authorizations will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

- Medical record documentation that member is compliant with the prescribed risdiplam regimen **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g., Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g., Spinraza)

***NOTE:** Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

If a formulary exception is approved, Evrysdi will be paid for under the member's prescription drug benefit.

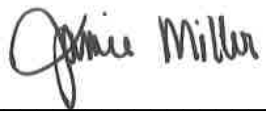
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 647.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Evrysdi**

Devised: 1/21/21
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 12/22/22 – removed age requirement
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 648.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Bafiertam**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bafiertam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Bafiertam may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30-day supply per fill

If a formulary exception is approved, Bafiertam will be paid for under the member's prescription drug benefit.

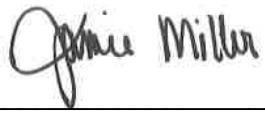
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 648.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Bafiertam |

**FORMULARY ALTERNATIVES:**
dimethyl fumarate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/22/21
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 649.0**

**SECTION: Commercial Drug**
**SUBJECT: Vumerity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vumerity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vumerity may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30-day supply per fill

If a formulary exception is approved, Vumerity will be paid for under the member's prescription drug benefit.

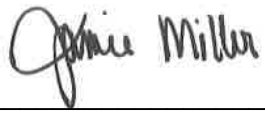
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 649.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Vumerity |

**FORMULARY ALTERNATIVES:**
dimethyl fumarate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/22/21 |
| Revised: | 3/1/21 – annual review, updated logo |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

| Geisinger | POLICY NUMBER: 650.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Enspryng |

**N**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Enspryng for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Enspryng may be made for members who meet the following criteria:

- Medical record documentation that Enspryng is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- **Initial Approval –** *Two authorizations must be entered.*
    - 120 once every 2 weeks for 3 doses, then 120 every 4 weeks
        1. In PA Hub: Add PA only.
        2. In NCRx: Add Ignore Misc Handler, DS, max number of claims authorized 1, max quantity dispensed 3, min day supply 28, max day supply 28, with a duration of two weeks.
            - QL FOR LETTER: Loading dose: 3 mL per 28 days; Maintenance dose: 1 mL per 28 days

- **Renewal –** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
    - QL FOR LETTER: 1 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

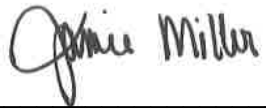
If a formulary exception is approved, Enspryng will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/22/21
Revised: 3/1/21 – annual review, updated logo, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered
Revised: 3/1/23 – annual review; updated signature title

Revised: 3/1/24 – annual review; updated auth entry parameters

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 651.0**

**SECTION: Commercial Drug**
**SUBJECT: Apomorphine**
**(generic Apokyn)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for apomorphine (generic Apokyn) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of apomorphine (generic Apokyn) may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Kynmobi within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Kynmobi

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved, apomorphine (generic Apokyn) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Kynmobi, carbidopa/levodopa/entacapone, entacapone, pramipexole, pramipexole extended release*, rasagiline, ropinirole, selegiline, tolcapone*, Inbrija

*prior authorization or step therapy required

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 651.0**

**SECTION: Commercial Drug**
**SUBJECT: Apomorphine**
**(generic Apokyn)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/22/21
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated to generic only

Geisinger

**POLICY NUMBER: 652.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ongentys**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ongentys for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ongentys may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of entacapone, carbidopa/levodopa/entacapone, or tolcapone within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to entacapone, carbidopa/levodopa/entacapone, or tolcapone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Ongentys will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

carbidopa/levodopa/entacapone, entacapone, pramipexole, pramipexole extended release*, rasagiline, ropinirole, selegiline, tolcapone*, Apokyn*, Inbrija, Kynmobi

*prior authorization or step therapy required

Geisinger

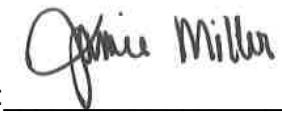
**POLICY NUMBER: 652.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ongentys**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/22/21 |
| Revised: | 3/1/21 – annual review, updated logo |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 653.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lampit**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lampit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Lampit may be made for members who meet the following criteria:

- Medical record documentation that Lampit is prescribed by an infectious disease specialist **AND**
- Medical record documentation of age less than or equal to 18 years **AND**
- Medical record documentation of weight greater than or equal to 2.5 kg **AND**
- Medical record documentation of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
    - Detection of circulating *T. cruzi* trypomastigotes on microscopy **OR**
    - Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
    - Two positive diagnostic serologic tests* using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 30 mg tablets: 9 tablets per day, 30 day-supply per fill
    - 120 mg tablets: 7.5 tablets per day, 30-day supply per fill

**AUTHORIZATION DURATION:** 60 days, RX count 2

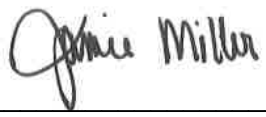
If a formulary exception is approved, Lampit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/26/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 654.0**

**SECTION: Commercial Drug**
**SUBJECT: Orgovyx**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orgovyx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Orgovyx may be made for members who meet the following criteria:

- Medical record documentation that Orgovyx is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of a diagnosis of advanced prostate cancer

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 64 tablets per 30 days

If a formulary exception is approved, Orgovyx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

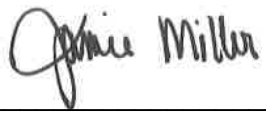
**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 654.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Orgovyx |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 3/26/21 |
| Revised: | 6/4/21 – removed reference to lung cancer |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 655.0**

**SECTION: Commercial Drug**
**SUBJECT: Xywav**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xywav for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xywav may be made for members who meet the following criteria:

**<u>Cataplexy or Excessive Daytime Sleepiness with Narcolepsy</u>**

- Medical record documentation of excessive daytime sleepiness in a patient with narcolepsy or cataplexy with narcolepsy **AND**
- Medical record documentation of therapeutic failure on modafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sodium oxybate (generic Xyrem) **OR**
    - Medical record documentation the patient requires a low sodium diet due to a concomitant diagnosis of heart failure, hypertension, or renal impairment

**<u>Idiopathic Hypersomnia</u>**

- Medical record documentation of a diagnosis of idiopathic hypersomnia **AND**
- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that member was evaluated and treated for other etiologies of excessive daytime sleepiness **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 18 mL per day, 30 day supply per fill

**AUTHORIZATION DURATION:**
Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

If an exception is made, Xywav will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
Narcolepsy: armodafinil*, modafinil*, dextroamphetamine, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release, sodium oxybate (generic Xyrem)*

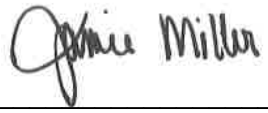
Idiopathic Hypersomnia: modafinil*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 655.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Xywav** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/26/21
Revised: 1/21/22 – updated indication criteria for narcolepsy, added hypersomnia indication, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated Xyrem to generic

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 656.0**

**SECTION: Commercial Drug**
**SUBJECT: Conjupri**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Conjupri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Conjupri may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Conjupri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

amlodipine, amlodipine/benazepril, Cartia XT, diltiazem, diltiazem extended release, felodipine extended release, nifedipine, Taztia XT, Tiadylt extended release, nifedipine extended release, verapamil, verapamil extended release

| Geisinger | POLICY NUMBER: 656.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Conjupri |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/4/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 657.0**

**SECTION: Commercial Drug**
**SUBJECT: Katerzia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Katerzia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Katerzia may be made for members who meet the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 mL per day

If an exception is made, Katerzia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

amlodipine, amlodipine/benazepril, Cartia XT, diltiazem, diltiazem extended release, felodipine extended release, nifedipine, Taztia XT, Tiadylt extended release, nifedipine extended release, verapamil, verapamil extended release

| Geisinger | POLICY NUMBER: 657.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Katerzia |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/4/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 658.0**

**SECTION: Commercial Drug**
**SUBJECT: Tepmetko**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tepmetko for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tepmetko may be made for members who meet the following criteria:

- Medical record documentation that Tepmetko is prescribed by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Tepmetko is configured as a prior authorization for new starts only. Tepmetko will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tepmetko will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

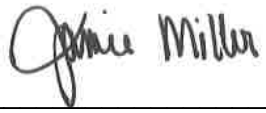
**FORMULARY ALTERNATIVES:**

Tabrecta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/4/21
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 660.0**

**SECTION: Commercial Drug**
**SUBJECT: Orladeyo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orladeyo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Orladeyo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that Orladeyo is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
    - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
    - Laryngeal edema **OR**
    - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
    - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
        - Low C4 levels **AND**
        - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
        - Less than 50% of the lower limit of normal C1-INH functions levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Orladeyo is being used as prophylactic therapy for hereditary angioedema (HAE) attacks **AND**

- Medical record documentation that Orladeyo is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze or Haegarda) or lanadelumab (Takhzyro) therapy for hereditary angioedema

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Orladeyo will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved, Orladeyo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

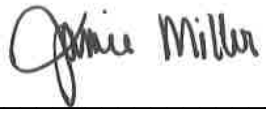
Haegarda*, Takhzyro*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 660.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Orladeyo** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/4/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 7/25/23 – removed Danazol requirement
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 661.0**

**SECTION: Commercial Drug**
**SUBJECT: Xolair for Self-Administration**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xolair for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xolair for self-administration may be made for members who meet the following criteria:

**Asthma**

- Medical record documentation that Xolair is prescribed by an allergist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that member is compliant with current therapeutic regimen **AND**
- Medical record documentation of diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e., greater than 12% improvement in forced expiratory volume in one second (FEV1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
- Medical record documentation of inadequate control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids or systemic corticosteroids **AND** long-acting beta agonists or leukotriene receptor antagonists **AND**
- Medical record documentation of the following:
    - For members age 12 and older, an IgE level of greater than 30 IU/ml and less than 700 IU/ml **OR**
    - For members age 6 through 11, an IgE level of greater than 30 IU/ml and less than 1300 IU/ml **AND**
- Medical record documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**

- Medical record documentation that Xolair will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Dupixent, Fasenra, Nucala, Cinqair, or Tezspire)

***NOTES**

Moderate persistent asthma is defined by the National Heart, Lung and Blood institute (NHLBI) as:

1. Daily symptoms
2. Daily use of inhaled short-acting beta agonist
3. Exacerbations affect activity
4. Exacerbations at least twice a week, which may last days
5. Nighttime symptoms more frequently than one time per week
6. Lung function of FEV1 greater than 60% but less than 80%

Severe persistent asthma is defined by the NHLBI as:

1. Continual symptoms
2. Limited physical activity
3. Frequent exacerbations
4. Frequent nighttime symptoms
5. Lung function of FEV1 less than or equal to 60% predicted

**The 12% improvement target value is calculated using the following methodology: The target value = baseline FEV1 x 1.12 The actual clinical calculation is: post-treatment FEV1 – baseline FEV1 = % improvement baseline FEV1

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 75 mg/0.5mL prefilled syringe: 5 mL per 28 days
  - 150 mg/1mL prefilled syringe: 4 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.

**Chronic Idiopathic Urticaria:**

- Medical record documentation that Xolair is prescribed by an allergist, immunologist, or dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of moderate-to-severe chronic idiopathic urticaria **AND**
- Medical record documentation of at least 6 week history of symptoms (e.g., hives associated with itching, angioedema) **AND**
- Medical record documentation of a therapeutic failure on Xolair 150 mg dose, when Xolair 300 mg dose is requested **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four week trial of ALL of the following treatment alternatives:
    - At least two different high dose antihistamines
    - Maximum dose antihistamine(s) used in combination with a leukotriene receptor antagonist (e.g., montelukast)
    - High dose antihistamine used in combination with H2 receptor antagonist (e.g., ranitidine
    - Dose advancement of potent antihistamine (e.g., hydroxyzine or doxepin)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- 150 mg every 4 weeks
    1. In PA Hub: Add PA, OQL, and max quantity dispensed 1.
        - QL FOR LETTER: 1 mL per 28 days

- 300 mg every 4 weeks
    1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.
        - QL FOR LETTER: 2 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.

**Nasal Polyps**

- Medical record documentation that Xolair is prescribed by or in consultation with an allergist, pulmonologist, immunologist or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years A**ND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

1. In PA Hub: Add PA, OQL, and max quantity dispensed 8.
    - QL FOR LETTER: 8 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.

If a formulary exception is approved, Xolair for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Asthma: dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, fluticasone HFA, Pulmicort Flexhaler, QVAR RediHaler, montelukast

Chronic Idiopathic Urticaria: hydroxyzine, doxepin, montelukast, ranitidine, cimetidine, famotidine

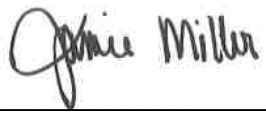
Nasal Polyps: fluticasone propionate, triamcinolone acetonide, mometasone furoate, Beconase AQ*, Qnasl*, Omnaris*, Zetonna*

*prior authorization required

| Geisinger | POLICY NUMBER: 661.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xolair for Self-Administration |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 6/7/21 |
| Revised: | 1/21/22 – updated how quantity limits are entered |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 4/6/22 – added prescribers for nasal polyps |
| Revised: | 6/7/22 – updated concurrent biologic criterion in asthma indication |
| Revised: | 1/20/23 – added 150 mg QL for urticaria |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 3/1/24 – annual review; updated FA |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 662.0**

**SECTION: Commercial Drug**
**SUBJECT: Fluoxetine for PMDD (generic Sarafem)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for fluoxetine for PMDD (generic Sarafem) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. ***PMDD*** – Premenstrual dysphoric disorder

**PROCEDURE:**

An exception for coverage of fluoxetine for PMDD (generic Sarafem) may be made for members who meet the following criteria:

- Medical record documentation of use for premenstrual dysphoric disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sertraline

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved, fluoxetine for PMDD (generic Sarafem) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

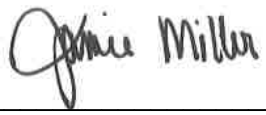
**FORMULARY ALTERNATIVES:**

paroxetine controlled release, sertraline

| Geisinger | POLICY NUMBER: 662.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Fluoxetine for PMDD (generic Sarafem) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/8/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 663.0**

**SECTION: Commercial Drug**
**SUBJECT: Fotivda**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fotivda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fotivda may be made for members who meet the following criteria:

- Medical record documentation that Fotivda is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) **AND**
- Medical record documentation of treatment with two or more prior systemic therapies

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 21 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Fotivda is configured as a prior authorization for new starts only. Fotivda will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Fotivda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

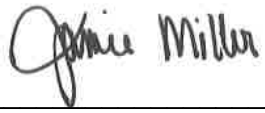
**FORMULARY ALTERNATIVES:**

everolimus*, Cabometyx*, Inlyta*, Lenvima*, sorafenib (generic Nexavar)*, sunitinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/1/21 |
| Revised: | 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated FA |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated FA; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 664.0**

**SECTION: Commercial Drug**
**SUBJECT: Imcivree**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Imcivree for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Imcivree may be made for members who meet the following criteria:

**<u>Obesity due to POMC, PCSK1, or LEPR Deficiency</u>**

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
    - For patients 18 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30 $kg/m^2$ **OR**
    - For patients 6 years to less than 18 years: Medical record documentation of weight greater than or equal to 95th percentile using growth chart assessments

**AND**

- Medical record documentation of a proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **AND**
- Medical record confirmation of genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)*

**<u>Obesity due to Bardet-Biedl Syndrome</u>**

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of obesity due to Bardet-Biedl syndrome (BBS)* **AND**
- Medical record documentation of one of the following:
    - For patients 16 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30$kg/m^2$

- For patients 6 years to less than 16 years: Medical record documentation of weight greater than or equal to 97th percentile using growth chart assessments

***NOTE:** Imcivree is not indicated for treatment of:

- Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1, LEPR deficiency, or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.3 mL per day

If a formulary exception is approved, Imcivree will be paid for under the member's prescription drug benefit.

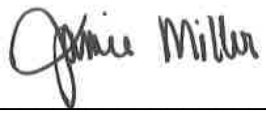
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 664.0**

**SECTION: Commercial Drug**
**SUBJECT: Imcivree**

Date: March 1, 2024

| | |
|---|---|
| Devised: | 7/1/21 |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 12/22/22 – added BBS indication |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 665.0**

**SECTION: Commercial Drug**
**SUBJECT: Klisyri**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Klisyri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Klisyri may be made for members who meet the following criteria:

- Medical record documentation that Klisyri is prescribed by a dermatologist **AND**
- Medical record documentation of actinic keratosis of the face or scalp **AND**
- Medical record documentation of greater than or equal to 4 lesions within a contiguous 25 $cm^2$ area **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND** imiquimod

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 package (5 packets) per fill

If a formulary exception is approved, Klisyri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

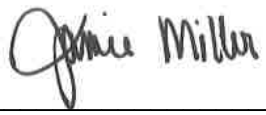
**FORMULARY ALTERNATIVES:**

fluorouracil cream/solution, imiquimod cream

| Geisinger | POLICY NUMBER: 665.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Klisyri |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 666.0**

**SECTION: Commercial Drug**
**SUBJECT: Diclofenac 3% Gel**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for diclofenac 3% gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of diclofenac 3% gel may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of actinic keratosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND** imiquimod

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If a formulary exception is approved, diclofenac 3% gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

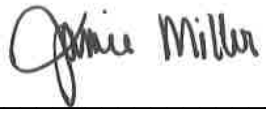
**FORMULARY ALTERNATIVES:**

fluorouracil cream/solution, imiquimod cream

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 666.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Diclofenac 3% Gel** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 667.0**

**SECTION: Commercial Drug**
**SUBJECT: Verquvo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verquvo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Verquvo may be made for members who meet the following criteria:

- Medical record documentation that Verquvo is prescribed by a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic chronic New York Heart Association Class II-IV heart failure **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of hospital admission due to heart failure within the previous 6 months **OR**
    - Medical record documentation of outpatient intravenous (IV) diuretic treatment for heart failure within the previous 3 months

**AND**

- Medical record documentation of a left ventricular ejection fraction (LVEF) less than or equal to 45% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary beta-blocker

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Verquvo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

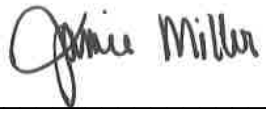
Angiotensin Converting Enzyme Inhibitor (ACEi)/Angiotensin Receptor Blocker (ARB): amlodipine/benazepril, benazepril, benazepril/hctz, candesartan, candesartan/hctz, captopril, captopril/hctz, enalapril, enalapril/hctz, fosinopril, irbesartan, irbesartan/hctz, lisinopril, lisinopril/hctz, losartan, losartan/hctz, moexipril, moexipril/hctz olmesartan, olmesartan/hctz, quinapril, telmisartan, telmisartan/hctz, trandolapril, ramipril, valsartan, valsartan/hctz

Angiotensin Receptor and Neprilysin Inhibitor (ARNI): Entresto

Beta-Blockers: acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, labetalol, metoprolol succinate, metoprolol tartrate, nadolol, pindolol, propranolol, timolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 10/6/22 – updated FA to include beta-blockers
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 668.0**

**SECTION: Commercial Drug**
**SUBJECT: Zokinvy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zokinvy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zokinvy may be made for members who meet the following criteria:

- Medical record documentation of a confirmed diagnosis through genetic testing of one of the following:
  - Hutchinson-Gilford Progeria Syndrome
  - Processing-deficient progeroid laminopathy with either:
    - Heterozygous LMNA mutation with progerin-like protein accumulation
    - Homozygous or compound heterozygous ZMPSTE24 mutations

**AND**

- Medical record documentation of age greater than or equal to 12 months **AND**
- Medical record documentation of body surface area of at least 0.39 $m^2$ **AND**
- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**

- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

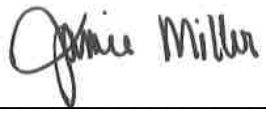
If a formulary exception is approved, Zokinvy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 669.0**

**SECTION: Commercial Drug**
**SUBJECT: Carbaglu**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Carbaglu for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Carbaglu may be made for members who meet the following criteria:

**N-acetylglutamate synthase (NAGS) deficiency**

- Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) **AND**
- Medical record documentation that Carbaglu is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AUTHORIZATION DURATION:** 6 months

**Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)**

- Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of propionic acidemia (PA) or methylmalonic acidemia (MMA) **AND**
- Medical record documentation of plasma ammonia level greater than or equal to 50 micromol/L **AND**
- Medical record documentation that Carbaglu is being prescribed as adjunctive treatment to standard of care (including but not limited to intravenous glucose, insulin, L-carnitine, protein restriction, and dialysis) **AND**
- Medical record documentation that Carbaglu is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

| Geisinger | POLICY NUMBER: 669.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Carbaglu |

**AUTHORIZATION DURATION:** 7 days

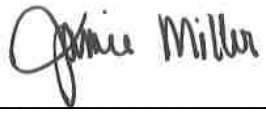
If a formulary exception is approved, Carbaglu will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 670.0**

**SECTION: Commercial Drug**
**SUBJECT: Asmanex and Qvar**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Asmanex and Qvar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Asmanex or Qvar may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Arnuity Ellipta or fluticasone diskus/HFA **AND** Pulmicort Flexhaler within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Arnuity Ellipta or fluticasone diskus/HFA **AND** Pulmicort Flexhaler

**MEDISPAN AUTHORIZATION LEVEL:**

- Asmanex – GPI-10
- Qvar – GPI-12

If a formulary exception is approved, Asmanex or Qvar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Arnuity Ellipta, fluticasone diskus, fluticasone HFA, Pulmicort Flexhaler

| Geisinger | POLICY NUMBER: 670.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Asmanex and Qvar |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated Flovent to generic

| Geisinger | POLICY NUMBER: 671.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lupkynis** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lupkynis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Lupkynis may be made for members who meet the following criteria:

- Medical record documentation that Lupkynis is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation that Lupkynis will be prescribed in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate mofetil (MMF) and corticosteroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Benlysta

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Medical record documentation of a positive clinical response to Lupkynis (e.g. improvement/stabilization in UPCR, eGFR, renal-related events) **AND**
- Medical record documentation that Lupkynis will be prescribed in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate mofetil (MMF) and corticosteroids)

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 capsules per day, 30 day supply per fill

If a formulary exception is approved, Lupkynis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

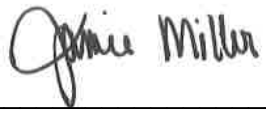
**FORMULARY ALTERNATIVES:**

Benlysta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/22/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 672.0**

**SECTION: Commercial Drug**
**SUBJECT: Metformin Extended Release (generic Fortamet and Glumetza)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for metformin extended release (generic Fortamet and Glumetza) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of metformin extended release (generic Fortamet and Glumetza) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin immediate release tablets **AND** metformin extended release tablets (generic Glucophage XR) at maximum dosage (2 grams per day = 4 tablets of 500 mg per day)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

If a formulary exception is approved, metformin extended release (generic Fortamet and Glumetza) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

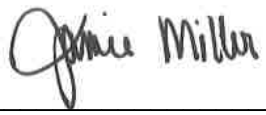
**FORMULARY ALTERNATIVES:**

metformin immediate release, metformin extended release (generic Glucophage XR)

| Geisinger | POLICY NUMBER: 672.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Metformin Extended Release<br>(generic Fortamet and Glumetza) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 8/24/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, defined IR & ER
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 673.0**

**SECTION: Commercial Drug**
**SUBJECT: Lumakras**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lumakras for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lumakras may be made for members who meet the following criteria:

- Medical record documentation that Lumakras is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a KRAS G12C mutation, as determined by a Food and Drug Administration (FDA)-approved test* **AND**
- Medical record documentation of treatment with at least one prior systemic therapy

***NOTE:** The Food and Drug Administration (FDA) approved tests for the detection of KRAS G12C mutation in NSCLC are the therascreen KRAS RGQ PCR Kit and Guardant 360® CDx.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Lumakras is configured as a prior authorization for new starts only. Lumakras will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Lumakras will be paid for under the member's prescription drug benefit.

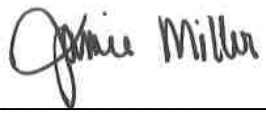
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 9/1/21 |
| Revised: | 11/29/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit. |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 674.0**

**SECTION: Commercial Drug**
**SUBJECT: Truseltiq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Truseltiq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Truseltiq may be made for members who meet the following criteria:

- Medical record documentation that Truseltiq is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by a Food and Drug Administration (FDA) approved test* **AND**
- Medical record documentation of one prior line of therapy

***NOTE:** The Food and Drug Administration (FDA) approved test can be found at http://www.fda.gov/CompanionDiagnostics.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Truseltiq 50 mg daily dose: 42 capsules per 28 days
  - Truseltiq 75 mg daily dose: 63 capsules per 28 days
  - Truseltiq 100 mg daily dose: 21 capsules per 28 days
  - Truseltiq 125 mg daily dose: 42 capsules per 28 days

**RE-AUTHORIZATION CRITERIA:** Truseltiq is configured as a prior authorization for new starts only. Truseltiq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Truseltiq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

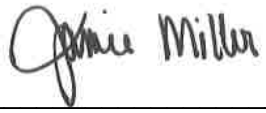
Pemazyre*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 674.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Truseltiq** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 9/1/21
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 675.0**

**SECTION: Commercial Drug**
**SUBJECT: Qelbree**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qelbree for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Qelbree may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to atomoxetine **OR** documentation that member has difficulty swallowing **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amphetamine-dextroamphetamine ER **AND** methylphenidate ER unless precluded by a valid pre-existing medical condition (e.g., personal or family history of substance use disorder, substance misuse, etc.) **AND**
- Medical record documentation of a prescribed dose that is consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature [max daily dose is 600 mg for ages 18 to 65; max daily dose is 400 mg for ages 6-17]

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Qelbree 100mg: 1 capsule per day
  - Qelbree 150 mg: 2 capsules per day
  - Qelbree 200 mg: 3 capsules per day

If a formulary exception is approved, Qelbree will be paid for under the member's prescription drug benefit.

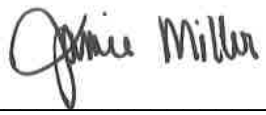
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atomoxetine, dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 4/7/23 – updated QL from tablets to capsules
Revised: 10/5/23 – updated 200 mg capsule QL to 3; added dosing criterion
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 676.0**

**SECTION: Commercial Drug**
**SUBJECT: Ezetimibe/Rosuvastatin**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ezetimibe/rosuvastatin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 469.0 Statin Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of ezetimibe/rosuvastatin may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of primary non-familial hyperlipidemia or homozygous familial hypercholesterolemia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on or intolerance to rosuvastatin **AND** ezetimibe used in combination

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, ezetimibe/rosuvastatin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

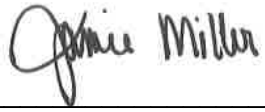
**FORMULARY ALTERNATIVES:**

rosuvastatin, ezetimibe, atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin

| Geisinger | POLICY NUMBER: 676.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ezetimibe/Rosuvastatin |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated to generic only

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 677.0**

**SECTION: Commercial Drug**
**SUBJECT: Zegalogue**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zegalogue for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zegalogue may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Glucagon emergency kit/injection **AND** Gvoke **AND** Baqsimi

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 units per fill (1.2 mL per fill)

If a formulary exception is approved, Zegalogue will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

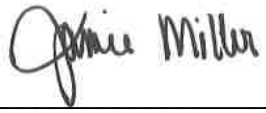
**FORMULARY ALTERNATIVES:**

Gvoke, Baqsimi, Glucagon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 677.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Zegalogue** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 678.0**

**SECTION: Commercial Drug**
**SUBJECT: Zeposia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zeposia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zeposia may be made for members who meet the following criteria:

**Multiple Sclerosis**

Note: *Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Multiple Sclerosis

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 7 Day Starter Pack: 7 capsules per 180 days
  - Starter Kit (7 Day Starter Pack and 0.92 mg 30 count bottle): 37 capsules per 180 days
  - 0.92 mg capsules: 1 capsule per day

**AUTHORIZATION DURATION:** Approval will be entered as an open-ended authorization.

**Ulcerative Colitis**

- Medical record documentation that Zeposia is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) preferred formulary biologics for the treatment of ulcerative colitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Entyvio **AND** infliximab **AND**
- Medical record documentation that Zeposia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 7 Day Starter Pack: 7 capsules per 180 days
  - Starter Kit (7 Day Starter Pack and 0.92 mg 30 count bottle): 37 capsules per 180 days
  - 0.92 mg capsules: 1 capsule per day

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ulcerative colitis at six (6) months of Zeposia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Zeposia therapy.

If a formulary exception is approved, Zeposia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 678.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Zeposia |

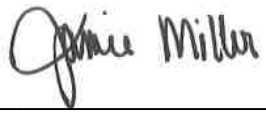
**FORMULARY ALTERNATIVES:**

Ulcerative Colitis: Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Rinvoq*, Xeljanz/XR*, Simponi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/1/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 1/1/23 – updated to allow Zeposia after failure of 2 preferred pharmacy benefit agents for UC
Revised: 3/1/23 – annual review; defined TNF; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 679.0**

**SECTION: Commercial Drug**
**SUBJECT: Desvenlafaxine ER (generic Khedezla)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for desvenlafaxine ER (generic Khedezla) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of desvenlafaxine ER (generic Khedezla) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to desvenlafaxine succinate ER (generic Pristiq)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, desvenlafaxine ER (generic Khedezla) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

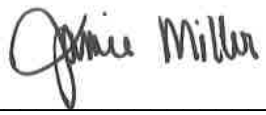
**FORMULARY ALTERNATIVES:**

desvenlafaxine succinate ER (generic Pristiq)

| Geisinger | POLICY NUMBER: 679.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Desvenlafaxine ER<br>(generic Khedezla) |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/12/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 680.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Welireg**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Welireg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Welireg may be made for members who meet the following criteria:

**Advanced Renal Cell Carcinoma**

- Medical record documentation that Welireg is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of von Hippel-Lindau (VHL) disease confirmed with a germline VHL alteration and at least one of the following:
    - associated renal cell carcinoma (RCC) **OR**
    - associated central nervous system (CNS) hemangioblastomas **OR**
    - associated pancreatic neuroendocrine tumors (pNET)

**AND**

- Medical record documentation that patient does not require immediate surgery

**Von Hippel-Lindau (VHL) Disease**

- Medical record documentation that Welireg is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of von Hippel-Lindau (VHL) disease confirmed with a germline VHL alteration and at least one of the following:
    - associated renal cell carcinoma (RCC) OR

- associated central nervous system (CNS) hemangioblastomas OR
- associated pancreatic neuroendocrine tumors (pNET)

**AND**

- Medical record documentation that patient does not require immediate surgery

**MEDISPAN APPROVAL LEVEL:** GPI-12, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 90 tablets per 30 days

**RE-AUTHORIZATION CRITERIA:** Welireg is configured as a prior authorization for new starts only. Welireg will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Welireg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

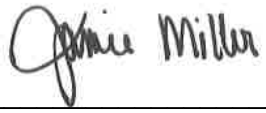
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 680.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Welireg** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 11/19/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review
Revised: 4/10/24 – added VHL indication; updated auth entry to 1 month duration

Geisinger

**POLICY NUMBER: 681.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: InPen**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for InPen for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of InPen may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that InPen is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 7 years **OR** age less than 7 years and documentation that InPen will be utilized with adult supervision **AND**
- Medical record documentation that member has access to a device with the ability to install and use the InPen app (e.g., smartphone, tablet, etc. with iOS 10 or later or Android 6 or later) **AND**
- Medical record documentation that member has utilized multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months **AND**
- Medical record documentation that member has suboptimal blood sugar control despite appropriate management as demonstrated by at least one of the following:
    - Glycosylated hemoglobin level (HbA1c) greater than 7.0%
    - History of recurring hypoglycemia
    - Wide fluctuations in blood glucose before mealtime
    - History of severe glycemic excursions

**MEDISPAN APPROVAL LEVEL:** NDC-11

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 pen per 365 days

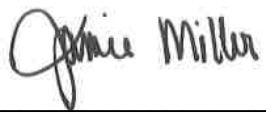
If a formulary exception is approved, InPen will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/19/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 682.0**

**SECTION: Commercial Drug**
**SUBJECT: Kerendia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kerendia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Kerendia may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Serum Potassium less than or equal to 5.0 MEQ/L **OR**
  - Serum Potassium less than or equal to 5.5 MEQ/L if already established on therapy **AND**
- Medical record documentation of persistent albuminuria (albumin to creatinine ratio consistently greater than 30 mg/g) despite treatment with both of the following:
  - Maximally tolerated angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) **AND**
  - One sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Kerendia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

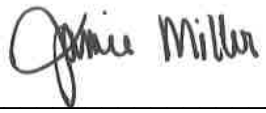
| Geisinger | POLICY NUMBER: 682.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Kerendia** |

**FORMULARY ALTERNATIVES:**

**ARB:** candesartan, losartan, irbesartan, olmesartan, telmisartan, valsartan
**ARB/diuretic combinations:** candesartan/hctz, irbesartan/hctz, losartan/hctz, olmesartan/hctz, telmisartan/hctz, valsartan/hctz
**ACE inhibitors:** benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, trandolapril, ramipril
**ACE inhibitors/diuretic combinations:** captopril/hctz, benazepril/hctz, enalapril/hctz, lisinopril/hctz, moexipril/hctz
**SLGT-2 Inhibitors:** Farxiga, Xigduo XR, Jardiance, Synjardy

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/19/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated FA; updated signature title
Revised: 7/25/23 – updated K+ criterion; updated to failure of an ACEi/ARB & one SGLT-2; updated FA
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 683.0**

**SECTION: Commercial Drug**
**SUBJECT: Lybalvi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lybalvi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lybalvi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lybalvi is being used for one of the following:
  - Schizophrenia **OR**
  - Acute treatment of manic or mixed episodes associated with bipolar I disorder **OR**
  - Maintenance treatment of bipolar I disorder

**AND**

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic, formulary atypical antipsychotics, one of which must be olanzapine

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Lybalvi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

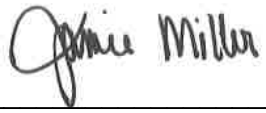
**FORMULARY ALTERNATIVES:**

aripiprazole, Caplyta*, Fanapt*, lurasidone (generic Latuda)*, Vraylar*, olanzapine, paliperidone*, quetiapine, risperidone, ziprasidone

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/22/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 684.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Myfembree** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Myfembree for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Myfembree may be made for members who meet the following criteria:

**<u>Heavy menstrual bleeding associated with uterine leiomyomas (fibroids)</u>**

- Medical record documentation that Myfembree is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior treatment to reduce menstrual bleeding, including but not limited to:
    - Oral contraceptives **OR**
    - Oral or injectable progesterone **OR**
    - Progestin-releasing intrauterine system **OR**
    - Tranexamic acid tablets **OR**
    - Gonadotropin-releasing hormone (GnRH) agonists

**<u>Endometriosis, moderate to severe pain</u>**

- Medical record documentation that Myfembree is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of moderate to severe pain associated with endometriosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one formulary extended-cycle contraceptive **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary nonsteroidal anti-inflammatory drugs (NSAIDs)

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 28 capsules per 28 days

**AUTHORIZATION DURATION:** Initial authorization will be 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix).

**REAUTHORIZATION:**

- Medical record documentation that the patient has not been treated for more than a total of 24 months with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix) **OR**
- Documentation of medical or scientific literature to support the use of this agent beyond the Food and Drug Administration (FDA)-approved treatment duration.

If a formulary exception is approved, Myfembree will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

<u>Heavy menstrual bleeding associated with uterine leiomyomas (fibroids):</u>
Afirmelle, Altavera, Alyacen, Amethia, Amethyst, Apri, Aranelle, Ashlyna, Aubra, Aurovela, Aurovela 24 FE, Aurovela FE, Aviane, Ayuna, Azurette, Balcoltra, Balziva, Beyaz, Blisovi 24 FE, Blisovi FE, Briellyn, Camila, Camrese, Camrese Lo, Charlotte 24 FE, Chateal, Cryselle, Cyred, Dasetta, Daysee, Deblitane, Delyla, Desogestrel/ethinyl estradiol, Dolishale, drospirenone/ethinyl estradiol/levomefolate, drospirenone/ethinyl estradiol, Elinest, Enpresse, Enskyce, Errin, Estarylla, ethynodiol/ethinyl estradiol, Falmina, Fayosim, Femynor, Gemmily, Generess FE, Hailey, Hailey 24 FE, Hailey FE, Heather, Iclevia, Incassia, Introvale, Isibloom, Jaimiess, Jasmiel, Jencycla, Jolessa, Juleber, Junel, Junel FE, Junel FE 24, Kaitlib FE, Kalliga, Kariva, Kelnor, Kurvelo, Larin, Larin 24 FE, Larin FE, Layolis FE, Leena, Lessina, Levonest, levonorgestrel/ethinyl estradiol, Levora, Loestrin, Loestrin FE, Lo Jaimiess, Lo Loestrin FE, Loryna, LoSeasonique, Low-Ogestrel, Lo-Zumandimine, Lutera, Lyleq, Lyza, Marlissa, Merzee, Microgestin, Microgestin 24 FE, Microgestin FE, Mili, Minastrin 24 FE, Mircette, Mono-

Linyah, Natazia, Necon, Nextstellis, Nikki, Nora-Be, norethindrone, norethindrone/ethinyl estradiol, norethindrone/ethinyl estradiol/ferrous fumarate, norgestimate/ethinyl estradiol, Norlyda, Norlyroc, Nortrel, Nylia, Nymyo, Ocella, Orsythia, Ortho Tri-Cyclen Lo, Philith, Pimtrea, Pirmella, Portia, Quartette, Reclipsen, Rivelsa, Safyral, Seasonique, Setlakin, Sharobel, Simliya, Simpesse, Slynd, Sprintec, Sronyx, Syeda, Tarina 24 FE, Tarina FE, Taysofy, Taytulla, Tilia FE, Tri-Femynor, Tri-Estarylla, Tri-Legest FE, Tri-Linyah, Tri-Lo-Estarylla, Tri-Legest FE, Tri-Linyah, Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Mili, Tri-Lo-Sprintec, Tri-Mili, Tri-Nymyo, Tri-Sprintec, Trivora-28, Tri-VyLibra, Tri-VyLibra Lo, Tyblume, Tydemy, Velivet, Vestura, Vienva, Viorele, Volnea, Vyfemla, VyLibra, Wera, Wymzya FE, Yasmin, Yaz, Zovia 1-35, Zumandimine, medroxyprogesterone acetate, tranexamic acid, Lupron Depot

Endometriosis, moderate to severe pain:
Extended Cycle Contraceptives: Amethia, Amethyst, Ashlyna, Camrese, Camrese Lo, Daysee, Dolishale, Fayosim, Introvale, Jaimiess, Jolessa, Lo Jaimiess, LoSeasonique, Quartette, Rivelsa, Seasonique, Setlakin, Simpesse, Medroxyprogesterone Acetate, and the intrauterine devices: Mirena, Liletta, Kyleena, Skyla, and ParaGard.

Nonsteroidal Anti-Inflammatory Drugs:
celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY NUMBER: 684.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Myfembree**

Devised: 11/22/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 1/19/23 – added endometriosis indication
Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 685.0**

**SECTION: Commercial Drug**
**SUBJECT: Oriahnn**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oriahnn for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Oriahnn may be made for members who meet the following criteria:

- Medical record documentation that Oriahnn is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior treatment to reduce menstrual bleeding, including but not limited to:
    - Oral contraceptives **OR**
    - Oral or injectable progesterone **OR**
    - Progestin-releasing intrauterine system **OR**
    - Tranexamic acid tablets **OR**
    - Gonadotropin-releasing hormone (GnRH) agonists

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 56 capsules per 28 days

**AUTHORIZATION DURATION:** Initial authorization will be 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix).

**REAUTHORIZATION:**

- Medical record documentation that the patient has not been treated for more than a total of 24 months with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix) **OR**
- Documentation of medical or scientific literature to support the use of this agent beyond the Food and Drug Administration (FDA)-approved treatment duration.

If a formulary exception is approved, Oriahnn will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

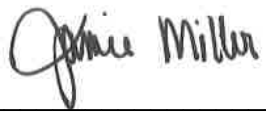
**FORMULARY ALTERNATIVES:**

Afirmelle, Altavera, Alyacen, Amethia, Amethyst, Apri, Aranelle, Ashlyna, Aubra, Aurovela, Aurovela 24 FE, Aurovela FE, Aviane, Ayuna, Azurette, Balcoltra, Balziva, Beyaz, Blisovi 24 FE, Blisovi FE, Briellyn, Camila, Camrese, Camrese Lo, Charlotte 24 FE, Chateal, Cryselle, Cyred, Dasetta, Daysee, Deblitane, Delyla, Desogestrel/ethinyl estradiol, Dolishale, drospirenone/ethinyl estradiol/levomefolate, drospirenone/ethinyl estradiol, Elinest, Enpresse, Enskyce, Errin, Estarylla, ethynodiol/ethinyl estradiol, Falmina, Fayosim, Femynor, Gemmily, Generess FE, Hailey, Hailey 24 FE, Hailey FE, Heather, Iclevia, Incassia, Introvale, Isibloom, Jaimiess, Jasmiel, Jencycla, Jolessa, Juleber, Junel, Junel FE, Junel FE 24, Kaitlib FE, Kalliga, Kariva, Kelnor, Kurvelo, Larin, Larin 24 FE, Larin FE, Layolis FE, Leena, Lessina, Levonest, levonorgestrel/ethinyl estradiol, Levora, Loestrin, Loestrin FE, Lo Jaimiess, Lo Loestrin FE, Loryna, LoSeasonique, Low-Ogestrel, Lo-Zumandimine, Lutera, Lyleq, Lyza, Marlissa, Merzee, Microgestin, Microgestin 24 FE, Microgestin FE, Mili, Minastrin 24 FE, Mircette, Mono-Linyah, Natazia, Necon, Nextstellis, Nikki, Nora-Be, norethindrone, norethindrone/ethinyl estradiol, norethindrone/ethinyl estradiol/ferrous fumarate, norgestimate/ethinyl estradiol, Norlyda, Norlyroc, Nortrel, Nylia, Nymyo, Ocella, Orsythia, Ortho Tri-Cyclen Lo, Philith, Pimtrea, Pirmella, Portia, Quartette, Reclipsen, Rivelsa, Safyral, Seasonique, Setlakin, Sharobel, Simliya, Simpesse, Slynd, Sprintec, Sronyx, Syeda, Tarina 24 FE, Tarina FE, Taysofy, Taytulla, Tilia FE, Tri-Femynor, Tri-Estarylla, Tri-Legest FE, Tri-Linyah, Tri-Lo-Estarylla, Tri-Legest FE, Tri-Linyah, Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Mili, Tri-Lo-Sprintec, Tri-Mili, Tri-Nymyo, Tri-Sprintec, Trivora-28, Tri-VyLibra, Tri-VyLibra Lo, Tyblume, Tydemy, Velivet, Vestura, Vienva, Viorele, Volnea, Vyfemla, VyLibra, Wera, Wymzya FE, Yasmin, Yaz, Zovia 1-35, Zumandimine, medroxyprogesterone acetate, tranexamic acid, Lupron Depot

| Geisinger | **POLICY NUMBER: 685.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Oriahnn** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 11/22/21
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 686.0**

**SECTION: Commercial Drug**
**SUBJECT: Wegovy and Zepbound**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Wegovy and Zepbound for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Pharmaceuticals for chronic weight management are not covered, except for certain clients that request this benefit.

An exception for coverage of Wegovy or Zepbound may be made for members who meet the following criteria:

- Medical record documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Wegovy or Zepbound **AND**
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of age greater than or equal to 18 years with one of the following:
        - Medical record documentation of body mass index (BMI) greater than or equal to 30 $kg/m^2$ **OR**
        - Medical record documentation of body mass index (BMI) greater than or equal to 27 $kg/m^2$ and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
    - For Wegovy only: Medical record documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex

**NOTE:** Wegovy and Zepbound are not indicated for treatment of chronic weight management:

- In combination with semaglutide or tirzepatide containing products or any other GLP-1 receptor agonist
- In combination with other products for weight loss, as safety and efficacy or coadministration has not been established
- In patients with acute pancreatitis. Use in caution in patients with history of pancreatitis.
- In patients with personal or family history of medullary thyroid C-cell carcinoma or Multiple Endocrine Neoplasia syndrome type 2
- In known hypersensitivity to semaglutide or tirzepatide or any of the excipients
- In pregnancy

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Wegovy: 3 mL per 28 days
  - Zepbound: 2 mL per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation that the member continues to experience clinical benefit from Wegovy or Zepbound based on the prescriber's assessment **AND**
- Medical record documentation that member has experienced at least a 5% reduction in weight from baseline

If an exception is made, Wegovy or Zepbound will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 686.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Wegovy and Zepbound |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| | |
|---|---|
| Devised: | 11/22/21 |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA |
| Revised: | 3/1/23 – annual review; updated signature title |
| Revised: | 6/5/23 – added indication for 12-18 years |
| Revised: | 10/6/23 – added lifestyle modifications & auth duration; updated formatting & note; corrected typo |
| Reviewed: | 3/1/24 – annual review |
| Revised: | 4/10/24 – added Zepbound to policy |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 687.0**

**SECTION: Commercial Drug**
**SUBJECT: Brexafemme**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Brexafemme for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Brexafemme may be made for members who meet the following criteria:

**Initial Treatment or New Infections of Vulvovaginal Candidiasis (VVC)**

- Medical record documentation of a diagnosis of vulvovaginal candidiasis (VVC) **AND**
- Medical record documentation that member is greater than or equal to 12 years of age and post-menarchal **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to oral fluconazole tablets **AND** one formulary topical antifungal indicated for the treatment of vulvovaginal candidiasis
- Medical record documentation that member is NOT pregnant

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 1 fill

**AUTHORIZATION DURATION:** 1 month, number of claims authorized = 1

**Reduction in the Incidence of Recurrent Vulvovaginal Candidiasis (RVVC)**

- Medical record documentation of diagnosis of recurrent vulvovaginal candidiasis (RVVC), defined as at least 3 episodes of VVC in the previous 12 months)* **AND**
- Medical record documentation that member is greater than or equal to 12 years of age and post-menarchal **AND**
- Medical record documentation that member is NOT pregnant **AND**
- Medical record documentation that pregnancy status will be reassessed prior to each dose **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to induction and maintenance** dosing of fluconazole tablets

***NOTE:** Treatments 1 and 2 are considered initial/new infection. If treatment 3 is within 12 months of treatments 1 and 2, would be considered RVVC.

****NOTE:** Induction and maintenance dosing is defined as fluconazole 150 mg orally every 72 hours for three doses, followed by maintenance oral fluconazole 150 mg once per week for six months.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, per 28 days

**AUTHORIZATION DURATION:** 6 months, number of claims authorized = 6

**REAUTHORIZATION**: Medical record documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration of 6 months. At time of review, the safety and efficacy of repeat administration of Brexafemme for RVVC has not been studied.

If a formulary exception is approved, Brexafemme will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 687.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Brexafemme** |

**FORMULARY ALTERNATIVES:**

fluconazole, miconazole 3 200 mg vaginal suppository, terconazole 0.41% cream, terconazole 0.8% cream, terconazole suppository

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/4/22 |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 6/5/23 – added RVVC indication; added pregnancy criterion to VV |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 688.0**

**SECTION: Commercial Drug**
**SUBJECT: Bylvay**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

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- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Bylvay may be made for members who meet the following criteria:

**Progressive Familial Intrahepatic Cholestasis (PFIC)**

- Medical record documentation that Bylvay is prescribed by or consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation of a diagnosis of progressive familial intrahepatic cholestasis (PFIC) confirmed by genetic testing **AND**
- Medical record documentation of the presence of moderate to severe pruritus **AND**
- Medical record documentation of age greater than or equal to 3 months **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the member's weight **AND**
- Medical record documentation of concurrent use or therapeutic failure on, intolerance to, or contraindication to ursodiol

***NOTE:** The recommended dosage of Bylvay for PFIC is 40 mcg/kg once daily. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg (6000 mcg). See https://bylvay.com/pdf/021066_Bylvay_Dosing_Guide.pdf

**Alagille Syndrome**

- Medical record documentation of a diagnosis of Alagille Syndrome (ALGS) **AND**
- Medical record documentation of the presence of moderate to severe pruritis **AND**
- Medical record documentation that member is 12 months of age or older **AND**
- Medical record documentation that Bylvay is prescribed by or in consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation that member is receiving an appropriate dose* based on the member's weight **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ursodiol and one of the following: cholestyramine, rifampin, or naltrexone

***NOTE: The recommended dosage of Bylvay for Alagille Syndrome is shown in the table below:**

**Table 2. Recommended Dosage for ALGS in Patients aged 12 months and older (120 mcg/kg/day)**

| Body Weight (kg) | Once Daily Dosage (mcg) |
|---|---|
| 7.4 and below | 600 |
| 7.5 to 12.4 | 1,200 |
| 12.5 to 17.4 | 1,800 |
| 17.5 to 25.4 | 2,400 |
| 25.5 to 35.4 | 3,600 |
| 35.5 to 45.4 | 4,800 |
| 45.5 to 55.4 | 6,000 |
| 55.5 and above | 7,200 |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 200 mcg pellets: 36 capsules per day, up to a 34 day supply per fill
  - 600 mcg pellets: 12 capsules per day, up to a 34 day supply per fill
  - 400 mcg capsules: 18 capsules per day, up to a 34 day supply per fill
  - 1200 mcg capsules: 6 capsules per day, up to a 34 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement in pruritus and/or reduction in serum bile acid **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the member's weight

If a formulary exception is approved, Bylvay will be paid for under the member's prescription drug benefit.

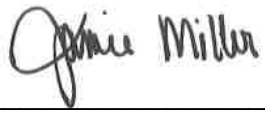
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ursodiol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/4/22 |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 11/1/23 – added Alagille syndrome indication; updated PFIC note; updated QL's |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY NUMBER: 689.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Exkivity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

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- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Exkivity may be made for members who meet the following criteria:

- Medical record documentation that Exkivity is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by a Food and Drug Administration (FDA)-approved test* **AND**
- Medical record documentation of disease progression on or after platinum-based chemotherapy

***NOTE:** The FDA approved test for detection of epidermal growth factor receptor (EGFR) exon 20 insertion mutations for Exkivity is the Oncomine Dx Target Test.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Exkivity will be configured as a prior authorization for new starts only. Exkivity will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Exkivity will be paid for under the member's prescription drug benefit.

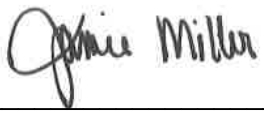
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/4/22
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; added PANSO to MediSpan approval language; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 690.0**

**SECTION: Commercial Drug**
**SUBJECT: Besremi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

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- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Besremi may be made for members who meet the following criteria:

- Medical record documentation that Besremi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of polycythemia vera **AND**
- Medical record documentation of an inadequate response or intolerance to hydroxyurea

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 mL per 28 days, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Besremi will be configured as a prior authorization for new starts only. Besremi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Besremi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
hydroxyurea

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/21/22
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/1/23 – annual review; added PANSO to MediSpan approval language; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 691.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Eprontia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Eprontia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Eprontia may be made for members who meet the following criteria:

**Seizures**

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut syndrome **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release tablets or topiramate immediate release sprinkle capsules **OR**
    - Medical record documentation of difficulty swallowing tablets **AND** therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release sprinkle capsules

**For Migraine prophylaxis**

- Medical record documentation of a diagnosis of use for migraine prophylaxis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release tablets or topiramate immediate release sprinkle capsule **OR**

- Medical record documentation of difficulty swallowing tablets **AND** therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release sprinkle capsules

**NOTE:** Topiramate immediate release sprinkle capsules may be opened and sprinkled over one teaspoon of soft food for immediate administration without chewing.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- 16 mL per day

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Eprontia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Seizures

For patients aged ≥ 2 years: topiramate immediate release tablets, topiramate immediate release sprinkle capsules, lamotrigine immediate release springle capsules, carbamazepine, levetiracetam IR, phenobarbital, phenytoin, pregabalin, topiramate extended release*

Additional Formulary Alternatives: gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

Migraine Prophylaxis

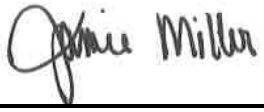
topiramate immediate release tablets, topiramate immediate release sprinkle capsules, metoprolol, propranolol, timolol, atenolol, nadolol, divalproex, sodium valproate, amitriptyline, venlafaxine, topiramate extended release*

*prior authorization required

| Geisinger | POLICY NUMBER: 691.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Eprontia |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

| | |
|---|---|
| Devised: | 1/21/22 |
| Revised: | 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered, updated FA |
| Revised: | 3/1/23 – annual review; updated signature |
| Reviewed: | 3/1/24 – annual review |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 692.0**

**SECTION: Commercial Drug**
**SUBJECT: Rezurock**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rezurock for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Rezurock may be made for members who meet the following criteria:

- Medical record documentation that Rezurock is prescribed by a hematologist, oncologist, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD) **AND**
- Medical record documentation of therapeutic failure of two or more prior lines of systemic therapy **AND**
- If request is for 200mg twice daily dosing, one of the following applies:
    - Medical record documentation that member is concurrently receiving a strong CYP3A4 inducer **OR**
    - If concurrently taking with a proton pump inhibitor (PPI), medical record documentation that treatment with a PPI is medically necessary **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to a H2 blocker

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

- 200 mg once daily: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill
- 200 mg twice daily: Only enter PA, OQL, max daily dose 2. QL FOR LETTER: 2 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval given for 6 months or less if the reviewing provider feels it is appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease. Subsequent approvals for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- If request is for 200mg twice daily dosing, one of the following applies:
  - Medical record documentation that member is concurrently receiving a strong CYP3A4 inducer **OR**
  - If concurrently taking with a proton pump inhibitor (PPI), medical record documentation that treatment with a PPI is medically necessary **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to a H2 blocker

If a formulary exception is approved, Rezurock will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

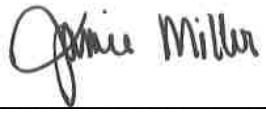
tacrolimus, cyclosporine, hydroxychloroquine, methotrexate, mycophenolate, sirolimus*, imatinib, Imbruvica*, Jakafi*, Rituxan*, Enbrel*, Lemtrada*, Orencia*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 692.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Rezurock** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/21/22
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 693.0**

**SECTION: Commercial Drug**
**SUBJECT: Scemblix**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Scemblix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Scemblix may be made for members who meet the following criteria:

- Medical record documentation that Scemblix is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) **AND** one of the following:
    - Medical record documentation of previous treatment with two or more tyrosine kinase inhibitors (TKIs) **OR**
    - Medical record documentation of a T315I cell mutation

**AND**

- If the requested dose is 200 mg twice daily: Medical record documentation of a T315I cell mutation

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:**

- 40 mg per day or 80 mg per day: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

- 200 mg twice daily (40 mg tablets): Only enter OQL, max daily dose 10. QL FOR LETTER: 10 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Scemblix will be configured as a prior authorization for new starts only. Scemblix will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Scemblix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

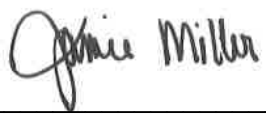
**FORMULARY ALTERNATIVES:**

imatinib, Bosulif*, Iclusig*, Sprycel*, Tasigna*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/21/22
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Revised: 3/1/23 – annual review; added PANSO to MediSpan approval language; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 694.0**

**SECTION: Commercial Drug**
**SUBJECT: Livmarli**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Livmarli for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Livmarli may be made for members who meet the following criteria:

- Medical record documentation that Livmarli is prescribed by or in consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation of diagnosis of Alagille Syndrome (ALGS) **AND**
- Medical record documentation of the presence of moderate to severe pruritus **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the member's weight **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ursodiol **AND** one of the following: cholestyramine, rifampin, naltrexone, sertraline

**NOTE:**

| Patient Weight (kg) | Days 1-7 (190 mcg/kg once daily) | | Beginning Day 8 (380 mcg/kg once daily) | |
|---|---|---|---|---|
| | Volume QD (mL) | Dosing dispenser size (mL) | Volume QD (mL) | Dosing dispenser size (mL) |
| **5 to 6** | 0.1 | 0.5 | 0.2 | 0.5 |
| **7 to 9** | 0.15 | | 0.3 | |
| **10 to 12** | 0.2 | | 0.45 | |
| **13 to 15** | 0.3 | | 0.6 | 1 |
| **16 to 19** | 0.35 | | 0.7 | |
| **20 to 24** | 0.45 | | 0.9 | |
| **25 to 29** | 0.5 | | 1 | |
| **30 to 34** | 0.6 | 1 | 1.25 | 3 |
| **35 to 39** | 0.7 | | 1.5 | |
| **40 to 49** | 0.9 | | 1.75 | |
| **50 to 59** | 1 | | 2.25 | |
| **60 to 69** | 1.25 | 3 | 2.5 | |
| **70 or higher** | 1.5 | | 3 | |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 3 mL per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement in pruritus from baseline **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight

If a formulary exception is approved, Livmarli will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

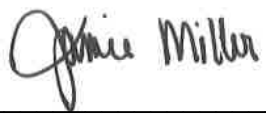
**FORMULARY ALTERNATIVES:**

ursodiol, cholestyramine, rifampin, naltrexone, sertraline, Bylvay*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 694.0**

**SECTION: Commercial Drug**
**SUBJECT: Livmarli**

Devised: 4/4/22
Revised: 3/1/23 – annual review; updated signature
Revised: 10/5/23 – removed age criterion
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 695.0**

**SECTION: Commercial Drug**
**SUBJECT: Opzelura**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Opzelura for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

**For the treatment atopic dermatitis**

An exception for coverage of Opzelura may be made for members who meet the following criteria:

- Medical record documentation that Opzelura is prescribed by or in consultation with a dermatologist, allergist, or immunologist **AND**
- Medical record documentation of a diagnosis of mild to moderate atopic dermatitis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that member is immunocompetent **AND**
- Medical record documentation of Body Surface Area (BSA) less than or equal to 20% **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other Janus-associated kinase (JAK) inhibitors or potent immunosuppressants such as azathioprine or cyclosporine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ALL of the following:
    - One formulary topical calcineurin inhibitor **AND**
    - One formulary topical corticosteroid unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) **OR** (b) member is less than 15 years of age **AND**
    - Eucrisa

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 240 grams per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences resolution of symptoms of atopic dermatitis. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of tolerability and positive clinical response to Opzelura **AND**
- Medical record documentation of symptomatic atopic dermatitis that requires additional treatment with Opzelura **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other Janus-associated kinase (JAK) inhibitors or potent immunosuppressants such as azathioprine or cyclosporine

**For the treatment of non-segmental vitiligo**
An exception for coverage of Opzelura may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of non-segmental vitiligo **AND**
- Medical record documentation that Opzelura is prescribed by or in consultation with a dermatologist, allergist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that other causes of depigmentation have been ruled out **AND**
- Medical record documentation that affected areas do not exceed 10% of body surface area **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary topical corticosteroid unless deemed inadvisable due to potential risks such as use on sensitive skin areas (face, axillae, groin) AND one topical calcineurin inhibitor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 240 grams per 28 days

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of tolerability and positive clinical response to Opzelura **AND**
- Medical record documentation of symptomatic nonsegmental vitiligo that requires additional treatment with Opzelura **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine

If a formulary exception is approved, Opzelura will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

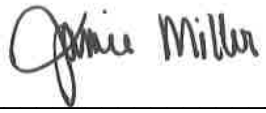
Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*
Eucrisa* (atopic dermatitis only)
Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)
Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 695.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Opzelura** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/4/22
Revised: 6/6/22 – removed references to Livmarli
Revised: 3/1/23 – annual review; updated signature
Revised: 2/12/24 – added non-segmental vitiligo indication
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 696.0**

**SECTION: Commercial Drug**
**SUBJECT: Qulipta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qulipta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Qulipta may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation that Qulipta will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
    - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/sodium valproate
    - Amitriptyline
    - Venlafaxine **AND**
- Medical record documentation that Qulipta will not be used in combination with botulinum toxin for the preventive treatment **OR**
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

**AUTHORIZATION DURATION:** Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Qulipta will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine **AND**
- Medical record documentation that Qulipta will not be used in combination with botulinum toxin for preventive treatment **OR**
    - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

If a formulary exception is approved, Qulipta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

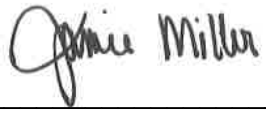
metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Aimovig*, Emgality*, Nurtec ODT*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 696.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Qulipta** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/4/22
Revised: 1/20/23 – updated to failure of 2 generic alts; updated to failure of 2 preferred CGRP's; removed prescriber requirement; removed diag based on ICHD 3 criteria; removed CGRF examples from concomitant use criteria, updated FA
Revised: 3/1/23 – annual review; updated signature
Revised: 7/25/23 – removed episodic migraine diagnosis criterion
Revised: 11/1/23 – removed failure of alternative CGRP's
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 697.0**

**SECTION: Commercial Drug**
**SUBJECT: Tavneos**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tavneos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tavneos may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis classified as one of the following variants:
  - granulomatosis with polyangiitis (GPA) **OR**
  - microscopic polyangiitis (MPA)

**AND**

- Medical record documentation of both of the following:
  - Medical record documentation of a positive test for anti-proteinase 3 (PR3) or anti-myeloperoxidase (MPO) **AND**
  - Medical record documentation of at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS)

**AND**

- Medical record documentation that Tavneos will be administered in combination with standard therapy such as, but not limited to rituximab, cyclophosphamide, methotrexate, mycophenolate, or azathioprine, and/or glucocorticoids

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be given for six months. Subsequent approvals will be for an additional twelve months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a reduction in the Birmingham Vasculitis Activity Score (BVAS) **AND**
- Medical record documentation that Tavneos will continue to be administered in combination with standard therapy such as, but not limited to rituximab, cyclophosphamide, methotrexate, mycophenolate, or azathioprine, and/or glucocorticoids

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

If a formulary exception is approved, Tavneos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

azathioprine, oral cyclophosphamide, methotrexate, mycophenolate, prednisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 697.0**

**SECTION: Commercial Drug**
**SUBJECT: Tavneos**

Devised: 4/4/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 698.0**

**SECTION: Commercial Drug**
**SUBJECT: Trudhesa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trudhesa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Trudhesa may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Trudhesa will be used for the acute treatment of moderate to severe migraine headaches with or without aura **AND**
- Medical record documentation of therapeutic failure on, in tolerance to, or contraindication to three (3) formulary alternatives, one of which must be dihydroergotamine nasal spray

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 12 mL per 28 days

If a formulary exception is approved, Trudhesa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 698.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Trudhesa |

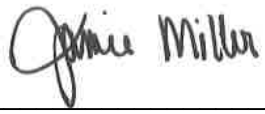
**FORMULARY ALTERNATIVES:**

dihydroergotamine nasal spray, zolmitriptan nasal spray, sumatriptan nasal spray, zolmitriptan tablets, sumatriptan tablets, naratriptan, rizatriptan, almotriptan*, eletriptan*, frovatriptan tablets*, Nurtec ODT*, Ubrelvy*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/4/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 699.0**

**SECTION: Commercial Drug**
**SUBJECT: Tyrvaya**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tyrvaya for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tyrvaya may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of dry eye disease **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Xiidra **AND** cyclosporine (generic Restasis)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8.4 mL per 30 days

If a formulary exception is approved, Tyrvaya will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

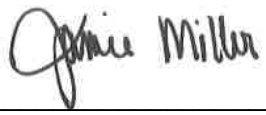
**FORMULARY ALTERNATIVES:**

Xiidra, cyclosporine (generic Restasis)

| Geisinger | **POLICY NUMBER: 699.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Tyrvaya** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/4/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 700.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Vuity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vuity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vuity may be made for members who meet the following criteria:

- Medical record documentation that Vuity is prescribed by or in consultation with an optometrist or ophthalmologist **AND**
- Medical record documentation of a diagnosis of presbyopia **AND**
- Medical record documentation of age greater than or equal to 40 years **AND**
- Medical record documentation of intolerance to or contraindication to corrective lenses

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2.5 mL per 30 days

If a formulary exception is approved, Vuity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

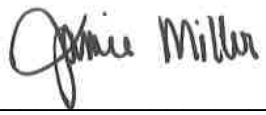
**FORMULARY ALTERNATIVES:**

none

| Geisinger | **POLICY NUMBER: 700.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Vuity** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/4/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 700.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Vuity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vuity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vuity may be made for members who meet the following criteria:

- Medical record documentation that Vuity is prescribed by or in consultation with an optometrist or ophthalmologist **AND**
- Medical record documentation of a diagnosis of presbyopia **AND**
- Medical record documentation of age greater than or equal to 40 years **AND**
- Medical record documentation of intolerance to or contraindication to corrective lenses

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2.5 mL per 30 days

If a formulary exception is approved, Vuity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

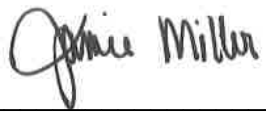
**FORMULARY ALTERNATIVES:**

none

| Geisinger | **POLICY NUMBER: 700.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Vuity** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/4/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 701.0**

**SECTION: Commercial Drug**
**SUBJECT: Adbry**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adbry for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Adbry may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation that Adbry is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
    - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable, therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals for the medication will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the patient experiences toxicity or worsening of disease.

**QUANTITY LIMIT:**

**Initial Approval** – Two authorizations must be entered.

- 600mg once, followed by 300mg every other week
    1. In NCRx: Add Treat As "Include" Process Modifier, Ignore Misc Handler, DS, enter 1 in max number of claims authorized, max quantity of 6, minimum day supply 28, and maximum day supply 28 with a duration of 2 weeks.
    2. In PA Hub: Add Treat As "Include" Process Modifier, Ignore Misc Handler, and max quantity 4 with a start date 1 day after the loading dose for remainder of the authorization.
        - QL FOR LETTER: Loading Dose: 6 mL per 28 days; Maintenance Dose: 4 mL per 28 days

**Renewal**

- 300mg every other week
    1. In PA Hub: Add Treat As "Include" Process Modifier, Ignore Misc Handler, and max quantity 4.
        - QL FOR LETTER: 4 mL per 28 days
- 300mg every 4 weeks
    1. In PA Hub: Add Treat As "Include" Process Modifier, Ignore Misc Handler, and max quantity 2.
        - QL FOR LETTER: 2 mL per 28 days

If a formulary exception is approved, Adbry will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

tacrolimus ointment

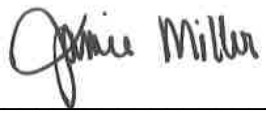
**Low-potency topical corticosteroids**: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

**Medium-potency topical corticosteroids**: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

**High-potency topical corticosteroids**: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)
**Very high-potency topical corticosteroids**: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/31/22
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated auth entry parameters

Geisinger

**POLICY NUMBER: 702.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Dhivy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dhivy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Dhivy may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Parkinson's disease, post-encephalitis parkinsonism, **OR** parkinsonism which may follow carbon monoxide intoxication or manganese intoxication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be immediate release carbidopa/levodopa

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 8 tablets per day

If a formulary exception is approved, Dhivy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

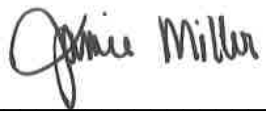
**FORMULARY ALTERNATIVES:**

carbidopa/levodopa ODT, carbidopa/levodopa tablet, carbidopa/levodopa ER tablet, carbidopa/levodopa/entacapone, pramipexole, ropinirole, ropinirole ER, bromocriptine, selegiline, amantadine, benztropine, trihexyphenidyl, rasagiline

| Geisinger | POLICY NUMBER: 702.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Dhivy |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/31/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 703.0**

**SECTION: Commercial Drug**
**SUBJECT: Livtencity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Livtencity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Livtencity may be made for members who meet the following criteria:

- Medical record documentation that Livtencity is prescribed by a transplant surgeon, infectious disease specialist, or hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years of age and weighs over 35 kilograms **AND**
- Medical record documentation that patient has received a hematopoietic stem cell transplant (HSCT), or solid organ transplant (SOT) **AND**
- Medical record documentation of a diagnosis of post-transplant cytomegalovirus (CMV) infection **AND**
- Medical record documentation that the members CMV infection is refractory to previous treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet **AND**
- Medical record documentation that medication will not be used in combination with another CMV antiviral **AND**
- If request is above 400 mg twice daily dosing, medical record documentation of one of the following:
    - For requests of 800 mg twice daily dosing: Medical record documentation that member is concurrently receiving carbamazepine **OR**
    - For requests of 1200 mg twice daily dosing: Medical record documentation that member is concurrently receiving phenytoin or phenobarbital

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** 8 weeks

| Geisinger | POLICY NUMBER: 703.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Livtencity** |

**NOTE:** Livtencity has not been studied in clinical trials for longer than 8 weeks and should only be used for treatment of active infection. Livtencity is not approved for prophylaxis of CMV infections.

**QUANTITY LIMIT:** 4 tablets per day, 28 day supply per fill

- 400 mg twice daily (given as two 200mg tablets twice daily): No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. QL FOR LETTER ONLY: 4 tablets per day
- 800 mg twice daily (given as four 200mg tablets twice daily): Only enter PA, OQL, max daily dose 8. QL FOR LETTER: 8 tablets per day
- 1200mg twice daily (given as six 200mg tablets twice daily): Only enter PA, OQL, max daily dose 12. QL FOR LETTER: 12 tablets per day

If a formulary exception is approved, Livtencity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
valganciclovir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

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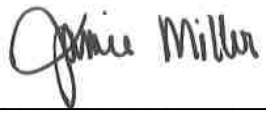
Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/31/22

Revised: 3/1/23 – annual review; defined kg; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 704.0**

**SECTION: Commercial Drug**
**SUBJECT: Recorlev**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Recorlev for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Recorlev may be made for members who meet the following criteria:

- Medical record documentation of endogenous hypercortisolemia associated with Cushing's syndrome **AND**
- Medical record documentation of age greater than or equal to 18 years older **AND**
- Medical record documentation that Recorlev is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, Metopirone, Signifor, Signifor LAR

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** 12 months. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 8 tablets per day, up to a 31 day supply per fill

If a formulary exception is approved, Recorlev will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

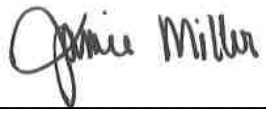
**FORMULARY ALTERNATIVES:**

ketoconazole oral tablets, Signifor LAR*, Signifor*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 5/31/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 705.0**

**SECTION: Commercial Drug**
**SUBJECT: Soaanz**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Soaanz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Soaanz may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Soaanz will be used for the treatment of edema associated with heart failure or renal disease **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be generic torsemide

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only:
  - 20 mg tablets: 1 tablet per day
  - 40 mg tablets: 2 tablets per day
  - 60 mg tablets: 3 tablets per day

If a formulary exception is approved, Soaanz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

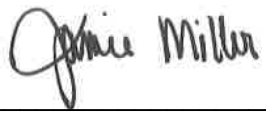
**FORMULARY ALTERNATIVES:**

torsemide, furosemide, bumetanide

| Geisinger | **POLICY NUMBER: 705.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Soaanz** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/7/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 706.0**

**SECTION: Commercial Drug**
**SUBJECT: Vonjo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vonjo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vonjo may be made for members who meet the following criteria:

- Medical record documentation that Vonjo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of severe thrombocytopenia with platelet count less than or equal to 50 x $10^9$/L **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of baseline total symptom score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Vonjo will not be used concurrently with other kinase inhibitors

**NOTE:** Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

- ✓ Age > 65 years
- ✓ WBC > 25 x $10^9$/L
- ✓ Hemoglobin < 10 g/dL
- ✓ Blood Blasts ≥ 1%
- ✓ Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- ✓ Transfusion dependency
- ✓ Platelets less than 100 X $10^9$/L
- ✓ Unfavorable karyotype

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 4 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Vonjo will no longer be covered if medical record documentation does not show:

- Medical record documentation of platelet count less than or equal to 50 x $10^9$/L **AND**
- The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

If a formulary exception is approved, Vonjo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

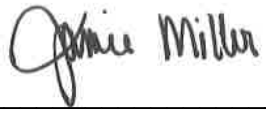
Jakafi*, Inrebic*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 706.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Vonjo** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/7/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 707.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Voxzogo |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Voxzogo GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Voxzogo may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3 **AND**
- Medical record documentation that Voxzogo is prescribed by a pediatric endocrinologist **AND**
- Medical record documentation that member is less than 18 years of age **AND**
- Medical record documentation of evidence that patient has open epiphyses **AND**
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery **AND**
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products **AND**
- Medical record documentation of glomerular filtration rate (GFR) greater than 60 ml/min/1.73m$^2$ **AND**
- Medical record documentation of member's current weight **AND**
- Medical record documentation that prescribed dose is appropriate for member's current weight **AND**
- Medical record documentation of baseline annualized growth velocity (AGV), calculated based on standing height measured over the course of 6 months prior to request

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 1 vial per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Voxzogo will no longer be covered if medical record documentation does not show:

- Medical record documentation of positive response to Voxzogo, as evidenced by improvement in annualized growth velocity (AGV) from baseline **AND**
- Medical record documentation of evidence that patient continues to have open epiphyses **AND**
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery **AND**
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products **AND**
- Medical record documentation of glomerular filtration rate (GFR) greater than 60 ml/min/1.73m$^2$ **AND**
- Medical record documentation of member's current weight **AND**
- Medical record documentation that prescribed dose is appropriate for member's current weight

If a formulary exception is approved, Voxzogo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

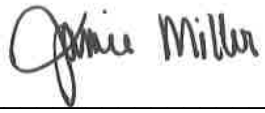
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 707.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Voxzogo** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 6/7/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review
Revised: 4/10/24 – updated age to less than 18 years

| Geisinger | POLICY NUMBER: 708.0 |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Duloxetine 40 mg (generic Irenka)** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for duloxetine 40 mg (generic Irenka) GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of duloxetine 40 mg (generic Irenka) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to duloxetine (generic Cymbalta) at the same dose as requested

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only

If a formulary exception is approved, duloxetine 40 mg (generic Irenka) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

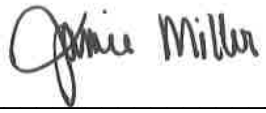
**FORMULARY ALTERNATIVES:**

duloxetine (generic Cymbalta)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 708.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Duloxetine 40 mg (generic Irenka) |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/7/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 709.0**

**SECTION: Commercial Drug**
**SUBJECT: Tarpeyo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tarpeyo GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tarpeyo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of primary immunoglobulin A nephropathy (IgAN) verified by biopsy **AND**
- Medical record documentation that Tarpeyo is prescribed by or in consultation with a nephrologist **AND**
- Medical record documentation that member is at high risk of disease progression, defined as urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 or proteinuria greater than or equal to 1 gram per day **AND**
- Medical record documentation of estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 $m^2$ **AND**
- Medical record documentation that member has received a stable dose of a renin-angiotensin system (RAS) Inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose for greater than or equal to 90 days **AND**
- Medical record documentation that a renin-angiotensin system (RAS) inhibitor (ACE inhibitor or ARB) will be used in combination with Tarpeyo **AND**
- Medical record documentation that member has received greater than or equal to 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification **AND**
- Medical record documentation that the member has not previously completed a 9-month treatment course of Tarpeyo **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a glucocorticoid (e.g., prednisone, methylprednisolone)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only: 4 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Approval will be for one, 10-month treatment cycle (or less if there is medical record documentation of an incomplete course of therapy).

If a formulary exception is approved, Tarpeyo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
methylprednisolone, prednisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/27/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 710.0**

**SECTION: Commercial Drug**
**SUBJECT: Vijoice**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vijoice GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vijoice may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) **AND**
- Medical record documentation of mutation in the catalytic α-subunit of PI3K (PIK3CA) gene **AND**
- Medical record documentation of severe or life-threatening disease which requires systemic treatment

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for letter only:
  - 50 mg tablet: 1 tablet per day, 28 day supply per fill
  - 125 mg tablet: 2 tablets per day, 28 day supply per fill
  - 250 mg therapy pack: 2 tablets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for **12 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

If a formulary exception is approved, Vijoice will be paid for under the member's prescription drug benefit.

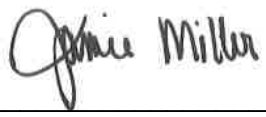
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/27/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 711.0**

**SECTION: Commercial Drug**
**SUBJECT: Cibinqo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cibinqo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

**For treatment of atopic dermatitis (AD)**
An exception for coverage of Cibinqo may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation that Cibinqo is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
    - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable: Therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure to one systemic therapy (e.g., Dupixent, Adbry) **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation that Cibinqo will not be used in combination with another Janus kinase (JAK) inhibitor, biologic immunomodulator or with other immunosuppressants including but not limited to azathioprine and cyclosporine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months if the reviewing provider feels it is medically appropriate. Subsequent approval will be for 12 months and will require medical record documentation of lack of disease progression or continued disease improvement.

If an exception is made, Cibinqo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Dupixent*
Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*
Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
High-potency topical corticosteroids: amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated signature
Revised: 6/5/23 – updated Dupixent criterion to reflect a systemic therapy for AD
Revised: 7/24/23 – updated age to 12 years
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 713.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ibsrela**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ibsrela for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ibsrela may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of irritable bowel syndrome with constipation (IBS-C) **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Linzess

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: 2 tablets per day

If an exception is made, Ibsrela will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Linzess

| Geisinger | POLICY NUMBER: 713.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ibsrela |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2023

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 714.0**

**SECTION: Commercial Drug**
**SUBJECT: Pyrukynd**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pyrukynd for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Pyrukynd may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of pyruvate kinase deficiency (PKD) **AND**
- Medical record documentation of at least 2 mutant alleles in the PKLR gene, with at least 1 being a missense mutation **AND**
- Medical record documentation that the member is not homozygous for the R479H mutation **AND**
- Medical record documentation that Pyrukynd is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation that the member required red blood cell (RBC) transfusions for hemolytic anemia due to PKD within the last 12 months **AND**
- Medical record documentation of hemoglobin level less than or equal to 10 g/dL

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months. Reauthorization requires medical documentation of an increase in hemoglobin of 1.5 g/dL from baseline **OR** reduction in transfusion burden.

**NOTE:** Abrupt discontinuation of Pyrukynd therapy may result in acute hemolysis.

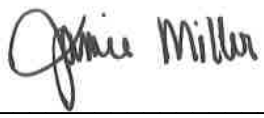
If an exception is made, Pyrukynd will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 715.0**

**SECTION: Commercial Drug**
**SUBJECT: Quviviq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Quviviq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Quviviq may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of insomnia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Quviviq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

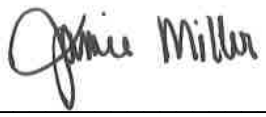
**FORMULARY ALTERNATIVES:**

zolpidem immediate release, zolpidem extended release, zaleplon, eszopiclone, quazepam, estazolam, flurazepam, temazepam, triazolam, zolpidem sublingual, ramelteon, doxepin (generic Silenor)

| Geisinger | POLICY NUMBER: 715.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Quviviq |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 716.0**

**SECTION: Commercial Drug**
**SUBJECT: Seglentis**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Seglentis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 488.0 Opioid Use
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Seglentis may be made for members who meet the following criteria:

- Medical documentation of age greater than or equal to 18 years **AND**
- Medical documentation of acute pain caused by medical condition **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary non-steroidal anti-inflammatory agents used in combination with tramadol, one of which must be celecoxib used in combination with tramadol

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: 4 tablets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** 28 days

If an exception is made, Seglentis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 716.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Seglentis |

**FORMULARY ALTERNATIVES:**

tramadol and celecoxib, tramadol and ibuprofen, tramadol and naproxen, tramadol and meloxicam

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 717.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Ztalmy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ztalmy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**
New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Ztalmy may be made for members who meet the following criteria:

- Medical record documentation that Ztalmy is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of CDKL5 Deficiency Disorder (CDD) **AND**
- Medical record documentation of genetic testing that confirms a cyclin-dependent kinase-like 5 (CDKL5) deficiency **AND**
- Medical record documentation that the patient is experiencing baseline seizures and documentation of the baseline frequency of seizures **AND**
- Medical record documentation of a therapeutic failure, intolerance, or contraindication to at least two previous antiepileptic therapies **AND**
- Medical record documentation that the requested daily dose does not exceed the following:
    - Weight less than 28 kg: 63 mg/kg/day **OR**
    - Weight greater than 28 kg: 1800 mg/day

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
QL FOR LETTER ONLY: 36.7 mL per day, 1100 mL per 30 days

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of the following:

- Medical record documentation of a sustained reduction in monthly seizure frequency compared to baseline **AND**
- Medical record documentation that the requested daily dose does not exceed the following:
  - Weight less than 28 kg: 63 mg/kg/day **OR**
  - Weight greater than 28kg: 1800 mg/day

If an exception is made, Ztalmy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

For patients aged ≥ 2 years: topiramate immediate release tablets, topiramate immediate release sprinkle capsules, lamotrigine immediate release springle capsules, carbamazepine, clobazam, levetiracetam IR, phenobarbital, phenytoin, pregabalin, topiramate extended release*, vigabatrin*, valproic acid

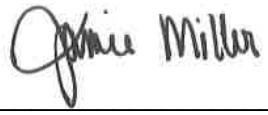
Additional Formulary Alternatives: gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 717.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Ztalmy** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 718.0 |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Non-Preferred Topical Corticosteroids** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for non-preferred topical corticosteroids for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of a non-preferred topical corticosteroid may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives [one (1) of which must be of a similar potency]

If a formulary exception is approved, the non-preferred topical corticosteroid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

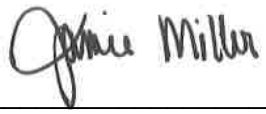
**FORMULARY ALTERNATIVES:**

**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone

0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/20/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 719.0**

**SECTION: Commercial Drug**
**SUBJECT: Alkindi Sprinkle**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alkindi Sprinkle for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Alkindi Sprinkle may be made for members who meet the following criteria:

- Medical record documentation of age less than or equal to 17 years **AND**
- Medical record documentation of a diagnosis of adrenocortical insufficiency **AND**
- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) generic formulary corticosteroid, one of which must be hydrocortisone

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Approval will be for 12 months. Members will be reassessed annually for age appropriateness and need for the sprinkle formulation.

If a formulary exception is approved, Alkindi Sprinkle will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

hydrocortisone, cortisone, dexamethasone, fludrocortisone, methylprednisolone, prednisone, prednisolone

| Geisinger | POLICY NUMBER: 719.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Alkindi Sprinkle |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/3/22
Revised: 3/1/23 – annual review; removed criteria from copy of steroid policy; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 720.0**

**SECTION: Commercial Drug**
**SUBJECT: Camzyos**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Camzyos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Camzyos may be made for members who meet the following criteria:

- Medical record documentation that Camzyos is prescribed by a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy **AND**
- Medical record documentation of left ventricular ejection fraction (LVEF) greater than or equal to 55% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: beta-blockers, non-dihydropyridine calcium channel blockers, or disopyramide

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: 1 capsule per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of the following:

- Medical record documentation of left ventricular ejection fraction (LVEF) greater than or equal to 50% **AND**
- Medical record documentation of clinical improvement or maintenance of condition

If an exception is made, Camzyos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Beta-blockers: acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, labetalol, metoprolol succinate, metoprolol tartrate, nadolol, pindolol, propranolol, timolol
Non-dihydropyridine calcium channel blockers diltiazem, verapamil
disopyramide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 721.0**

**SECTION: Commercial Drug**
**SUBJECT: Dartisla ODT**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dartisla ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Dartisla ODT may be made for members who meet the following criteria:

- Medical record documentation that Dartisla ODT will be given as an adjunct to treatment of peptic ulcer disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of difficulty swallowing **OR**
  - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glycopyrrolate tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
QL FOR LETTER ONLY: 4 tablets per day

If an exception is made, Dartisla ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

glycopyrrolate tablets

| Geisinger | POLICY NUMBER: 721.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Dartisla ODT |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 722.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Jatenzo, Tlando, and Kyzatrex**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jatenzo, Tlando, and Kyzatrex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Jatenzo, Tlando, or Kyzatrex may be made for members who meet the following criteria:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
  - Primary hypogonadism (congenital or acquired) **OR**
  - Hypogonadotropic hypogonadism (congenital or acquired)

**AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Jatenzo 158 mg or 198 mg capsules: 4 capsules per day
  - Jatenzo 237 mg capsules: 2 capsules per day
  - Tlando: 2 capsules per day
  - Kyzatrex 100 mg capsule: 2 capsules per day
  - Kyzatrex 150 mg or 200 mg capsule: 4 capsules per day

If an exception is made, Jatenzo, Tlando, or Kyzatrex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

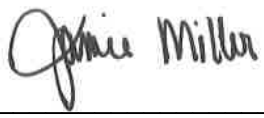
**FORMULARY ALTERNATIVES:**

testosterone gel, testosterone transdermal gel, testosterone transdermal solution, testosterone cypionate injection, testosterone enanthate injection, Aveed*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 1/1/23 – removed reference to Camzyos
Revised: 3/1/23 – annual review; updated signature
Revised: 6/5/23 – added Kyzatrex to policy; updated FA
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 723.0**

**SECTION: Commercial Drug**
**SUBJECT: Norliqva**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Norliqva for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Norliqva may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 mL per day

If an exception is made, Norliqva will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

amlodipine oral tablets, verapamil, nifedipine ER, diltiazem, diltiazem ER, felodipine, isradipine, nicardipine, nisoldipine

| Geisinger | POLICY NUMBER: 723.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Norliqva |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 724.0**

**SECTION: Commercial Drug**
**SUBJECT: Radicava ORS**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Radicava ORS for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Radicava ORS may be made for members who meet the following criteria:

- Medical record documentation that Radicava ORS is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
- Medical record documentation of baseline functional status (as evidenced by a scoring system such as the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.) **AND**
- Medical record documentation that Radicava is being given in combination with riluzole **OR** intolerance or contraindication to riluzole

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Radicava ORS Starter Kit: 70 mL per 180 days
  - Radicava ORS Maintenance: 50 mL per 28 days

| Geisinger | POLICY NUMBER: 724.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Radicava ORS** |

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation that member is tolerating and compliant with prescribed edaravone regimen **AND**
- Medical record documentation of regular physician follow-up

If an exception is made, Radicava ORS will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

riluzole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 725.0**

**SECTION: Commercial Drug**
**SUBJECT: Verkazia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verkazia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Verkazia may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of vernal keratoconjunctivitis in children and adults **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to at least one mast cell stabilizer/topical antihistamine (i.e., olopatadine, azelastine, epinastine)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 single-dose vials per day

If an exception is made, Verkazia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

olopatadine 0.1% ophthalmic, olopatadine 0.2% ophthalmic, azelastine 0.05% ophthalmic, epinastine 0.05% ophthalmic, cyclosporine 0.05% ophthalmic emulsion, cromolyn 4% ophthalmic

| Geisinger | POLICY NUMBER: 725.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Verkazia |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 726.0**

**SECTION: Commercial Drug**
**SUBJECT: Xyosted**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xyosted for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xyosted may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
  - Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
    - Primary hypogonadism (congenital or acquired) **OR**
    - Hypogonadotropic hypogonadism (congenital or acquired) **OR**
  - Medical record documentation of a diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Xyosted will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

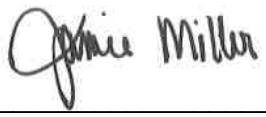
**FORMULARY ALTERNATIVES:**

testosterone cypionate injection, testosterone enanthate injection, testosterone transdermal gel

| Geisinger | POLICY NUMBER: 726.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xyosted |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/22
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

| Geisinger | POLICY NUMBER: 727.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Adlarity** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adlarity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Adlarity may be made for members who meet the following criteria:

**Mild to Moderate Dementia**

- Medical record documentation of a diagnosis of mild to moderate dementia of Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be oral donepezil

**Severe Dementia**

- Medical record documentation of a diagnosis of severe dementia of Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, or contraindication to donepezil tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 transdermal patches per 28 days

If an exception is made, Adlarity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

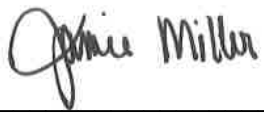
| Geisinger | POLICY NUMBER: 727.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Adlarity |

**FORMULARY ALTERNATIVES:**

donepezil tablets, donepezil ODT, galantamine tablets, galantamine ER capsules, rivastigmine capsules

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/5/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 728.0**

**SECTION: Commercial Drug**
**SUBJECT: CaroSpir**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for CaroSpir for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of CaroSpir may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary diuretics, one of which must be spironolactone tablets **OR**
  - If the member has trouble swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to furosemide oral liquid **OR**
  - If the member has trouble swallowing, medical record documentation of a diagnosis of heart failure

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 20 mL per day

If an exception is made, CaroSpir will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 728.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: CaroSpir |

**FORMULARY ALTERNATIVES:**

Loop diuretics: bumetanide, furosemide (tablets, solution), torsemide

Potassium sparing diuretics: spironolactone tablets, spironolactone/hydrochlorothiazide, eplerenone, amiloride, amiloride/hydrochlorothiazide, triamterene/hydrochlorothiazide

Thiazide diuretics: hydrochlorothiazide, indapamide, metolazone, chlorthalidone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/5/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 729.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Elyxyb** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Elyxyb for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Elyxyb may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of migraine with or without aura **AND**
- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to celecoxib capsules **AND** two (2) additional formulary alternatives **OR**
    - If a barrier or difficulty with swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to celecoxib capsules **AND** two (2) additional formulary liquid non-steroidal anti-inflammatory drug (NSAID) alternatives

**NOTE:** Per celecoxib package insert: “For patients that have difficulty swallowing capsules, the contents of a Celebrex capsule can be added to applesauce. The entire capsule contents are carefully emptied onto a level teaspoon of cool or room temperature applesauce and ingested immediately with water. The sprinkled capsule contents on applesauce are stable for up to 6 hours under refrigerated conditions (2-8° C/ 35-45° F).

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 144 mL per 30 days

If an exception is made, Elyxyb will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/5/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 730.0**

**SECTION: Commercial Drug**
**SUBJECT: Eysuvis**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Eysuvis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Eysuvis may be made for members who meet the following criteria:

- Medical record documentation that Eysuvis is prescribed by an optometrist or ophthalmologist **AND**
- Medical record documentation that Eysuvis is being used for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease **AND**
- Medical record documentation that Eysuvis will be prescribed according to the Food and Drug Administration (FDA) approved dose* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to loteprednol 0.5% suspension** **OR** fluorometholone 0.1% suspension

**NOTE:** The FDA approved dose is one to two drops into each eye four times daily for up to two weeks.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**AUTHORIZATION DURATION:** 14 days, RX count 1

**QUANTITY LIMIT:** *QLs must be entered within the authorization.*
QL FOR LETTER AND AUTHORIZATION: 8.3 mL per 14 days, minimum and maximum day supply 14 days.

If an exception is made, Eysuvis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 730.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Eysuvis |

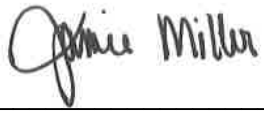
**FORMULARY ALTERNATIVES:**

loteprednol 0.5% suspension*, fluorometholone 0.1% suspension

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 731.0**

**SECTION: Commercial Drug**
**SUBJECT: Gloperba**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gloperba for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Gloperba may be made for members who meet the following criteria:

- Medical record documentation of age 18 great than or equal to years **AND**
- Medical record documentation that Gloperba is being used for prophylaxis of gout flares **AND**
- Medical record documentation that Gloperba will be used in combination with urate lowering therapy (ULT) **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of difficulty swallowing **OR**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary anti-inflammatory gout prophylactic agents, one of which much be generic colchicine tablets **OR** generic colchicine capsules

**NOTE:** Medical record documentation that member is not currently prescribed drugs that inhibit both CYP3A4 and P-gp if they have renal or hepatic impairment.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 mL per day

**AUTHORIZATION DURATION:** 6 months

If an exception is made, Gloperba will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

colchicine, celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac tromethamine, meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin, dexamethasone, fludrocortisone, hydrocortisone, methylprednisolone, prednisolone, prednisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 732.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Preferred GLP-1 Agonists and Mounjaro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mounjaro, Ozempic, Rybelsus, Trulicity, and Victoza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Mounjaro, Ozempic, Rybelsus, Trulicity, or Victoza may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY:

- Mounjaro 2.5 mg: 2 mL per 180 days
- Mounjaro 5 mg, 7.5 mg, 10 mg, 12.5 mg, & 15 mg: 2 mL per 28 days
- Ozempic: 3 mL per 28 days
- Rybelsus 3 mg: 30 tablets per 180 days
- Rybelsus 7 mg & 14 mg: 1 tablet per day
- Trulicity: 2 mL per 28 days
- Victoza: 9 mL per 28 days

If an exception is made, Mounjaro, Ozempic, Rybelsus, Trulicity, or Victoza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 732.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Preferred GLP-1 Agonists and Mounjaro |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| | |
|---|---|
| Devised: | 12/6/22 |
| Revised: | 3/1/23 – annual review; updated signature |
| Revised: | 11/1/23 – updated Ozempic titration pen QL to 3 mL/28 days |
| Reviewed: | 3/1/24 – annual review |
| Revised: | 4/10/24 – updated Mounjaro and Ozempic QL's |

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 733.0**

**SECTION: Commercial Drug**
**SUBJECT: Baclofen Oral Solution (generic Ozobax), Fleqsuvy, & Lyvispah**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for baclofen oral solution (generic Ozobax), Fleqsuvy, and Lyvispah for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of baclofen oral solution (generic Ozobax), Fleqsuvy, or Lyvispah may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of spasticity from multiple sclerosis **OR** spinal cord injuries and/or diseases **AND**
- Medical record documentation of an age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of inability to tolerate or swallow tablets **OR**
  - Medical record documentation of therapeutic failure on, or contraindication to the preferred formulary alternatives, both baclofen tablets and tizanidine tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14, generic only if request is for baclofen oral solution (generic Ozobax)

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Baclofen Oral Solution (generic Ozobax) & Fleqsuvy: 16 mL per day
  - Lyvispah: 4 packets per day

If an exception is made, baclofen oral solution (generic Ozobax), Fleqsuvy, or Lyvispah will be paid for under the member's prescription drug benefit.

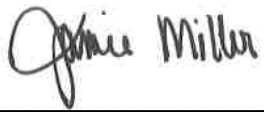
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 733.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Baclofen Oral Solution (generic Ozobax), Fleqsuvy, & Lyvispah |

**FORMULARY ALTERNATIVES:**
baclofen tablets, tizanidine tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Revised: 4/7/23 – added Fleqsuvy & Lyvispah to policy
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 734.0**

**SECTION: Commercial Drug**
**SUBJECT: Rasuvo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rasuvo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Rasuvo may be made for members who meet the following criteria:

**Rheumatoid Arthritis**

- Medical record documentation of treatment of severe, active rheumatoid arthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior first line therapy (including NSAIDs) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate vials

**For Polyarticular Juvenile Idiopathic Arthritis:**

- Medical record documentation of treatment of active polyarticular juvenile idiopathic arthritis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior first line therapy (including NSAIDs) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate vials

**For Psoriasis:**

- Medical record documentation of treatment of severe, recalcitrant, disabling psoriasis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate vials

| Geisinger | POLICY NUMBER: 734.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Rasuvo** |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

If an exception is made, Rasuvo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

methotrexate vials, methotrexate tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 735.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Voquezna**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Voquezna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Voquezna may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of *Helicobacter pylori (H. pylori)* infection **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies for *Helicobacter pylori (H. pylori)* infection

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 112 tablets/capsules per 14 days

**AUTHORIZATION DURATION:** 14 days, RX count 1

If an exception is made, Voquezna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

amoxicillin, clarithromycin, levofloxacin, metronidazole, rifabutin, tetracycline, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole

| Geisinger | POLICY NUMBER: 735.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Voquezna |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 736.0**

**SECTION: Commercial Drug**
**SUBJECT: Vtama**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vtama for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vtama may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one (1) medication from all of the following:
  - Topical corticosteroid (at least medium or higher potency) **OR** topical calcineurin inhibitor **AND**
  - Topical retinoid **AND**
  - Topical vitamin D analog

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Vtama will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Topical Vitamin D Analogs: calcipotriene 0.005% solution/cream/ointment (Dovonex), calcitriol 3mcg/gm ointment (Vectical)

Topical Retinoids: tazarotene 0.1% cream/gel (Tazorac)

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe);

hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)

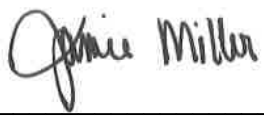
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 736.0**

**SECTION: Commercial Drug**
**SUBJECT: Vtama**

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 737.0**

**SECTION: Commercial Drug**
**SUBJECT: ZTlido**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ZTlido for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of ZTlido may be made for members who meet the following criteria:

- Medical record documentation of a Food and Drug Administration (FDA) approved indication (post-herpetic neuralgia) **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to a gabapentinoid (gabapentin or pregabalin) **AND** lidocaine 5% patches

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 patches per day

If an exception is made, ZTlido will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

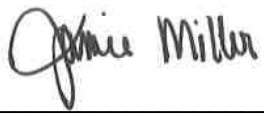
lidocaine 5% patches*, gabapentin, pregabalin

*prior authorization required

| Geisinger | POLICY NUMBER: 737.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: ZTlido |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/6/22
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 738.0**

**SECTION: Commercial Drug**
**SUBJECT: Xatmep**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xatmep for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xatmep may be made for members who meet the following criteria:

**Juvenile Idiopathic Arthritis**

- Medical record documentation of age less than or equal to 18 years **AND**
- Medical record documentation of polyarticular juvenile idiopathic arthritis following an insufficient response or intolerance to a 3-month trial of a formulary NSAID or other first line therapy

**Acute Lymphoblastic Leukemia**

- Medical record documentation of age less than or equal to 18 years **AND**
- Medical record documentation of acute lymphoblastic leukemia used as part of a combination chemotherapy maintenance regimen

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Xatmep will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 738.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xatmep |

**FORMULARY ALTERNATIVES:**

Juvenile Idiopathic Arthritis: methotrexate tablets, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 12/8/22
Revised: 3/1/23 – annual review; updated FA; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 739.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Entadfi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Entadfi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Entadfi may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of benign prostatic hyperplasia (BPH) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three therapy regimens for benign prostatic hyperplasia (BPH), one of which must be tadalafil in combination with finasteride **AND**
- Medical record documentation that the member did not exceed 26 weeks of therapy of finasteride in combination with tadalafil

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

**AUTHORIZATION DURATION:** 26 weeks

**RE-AUTHORIZATION CRITERIA:** For requests exceeding 26 weeks durations, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the Food and Drug Administration (FDA)-approved treatment duration.

If an exception is made, Entadfi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 739.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Entadfi |

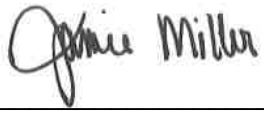
**FORMULARY ALTERNATIVES:**

finasteride, tadalafil 2.5 mg*, tadalafil 5 mg*, dutasteride, alfuzosin, tamsulosin

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/20/23
Revised: 3/1/23 – annual review; updated FA; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY NUMBER: 740.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Lytgobi**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lytgobi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lytgobi may be made for members who meet the following criteria:

- Medical record documentation that Lytgobi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by molecular testing **AND**
- Medical record documentation of one prior line of therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - Lytgobi 12 mg daily dose: 84 tablets per 28 days
  - Lytgobi 16 mg daily dose: 112 tablets per 28 days
  - Lytgobi 20 mg daily dose: 140 tablets per 28 days

| Geisinger | POLICY NUMBER: 740.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Lytgobi** |

**RE-AUTHORIZATION CRITERIA:** Lytgobi is configured as a prior authorization for new starts only. Lytgobi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Lytgobi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

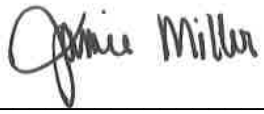
**FORMULARY ALTERNATIVES:**

Pemazyre*, Truseltiq*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/20/23
Revised: 3/1/23 – annual review; added PANSO to MediSpan approval language; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 741.0**

**SECTION: Commercial Drug**
**SUBJECT: Ryaltris**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ryaltris for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ryaltris may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of allergic rhinitis **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to intranasal olopatadine in combination with intranasal mometasone **AND** azelastine/fluticasone intranasal

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.96 g per day (29 g per 30 days)

If an exception is made, Ryaltris will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

fluticasone propionate nasal spray, mometasone nasal spray, azelastine 0.1% nasal spray, azelastine 0.15% nasal spray, olopatadine nasal spray, azelastine/fluticasone nasal spray

| Geisinger | POLICY NUMBER: 741.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ryaltris |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/20/23
Revised: 3/1/23 – annual review; updated signature
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 742.0**

**SECTION: Commercial Drug**
**SUBJECT: Sotyktu**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sotyktu for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Sotyktu may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Sotyktu is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to or therapeutic failure on four (4) preferred formulary biologics for the treatment of psoriasis **AND**
- Medical record documentation that Sotyktu is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical

improvement or lack of progression in signs and symptoms of plaque psoriasis on Sotyktu therapy is required.

If an exception is made, Sotyktu will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

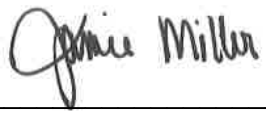
**FORMULARY ALTERNATIVES:**

Enbrel*, Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Otezla*, Skyrizi*, Tremfya*, Cosentyx*, Cimzia*, Siliq*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/20/23
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 743.0**

**SECTION: Commercial Drug**
**SUBJECT: Tadliq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tadliq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tadliq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of pulmonary arterial hypertension (PAH) **AND**
- Medical record documentation that prescription is written by a pulmonologist or cardiologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sildenafil **AND** tadalafil tablets **OR**
- If the member has trouble swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to sildenafil oral liquid

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 mL per day, 30 day supply per fill

If an exception is made, Tadliq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 743.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tadliq |

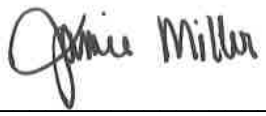
**FORMULARY ALTERNATIVES:**

sildenafil tablets (generic Revatio)*, sildenafil oral liquid (generic Revatio)*, tadalafil tablets (generic Adcirca)*, Liqrev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 1/20/23
Revised: 3/1/23 – annual review; updated signature
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY NUMBER: 744.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zoryve**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zoryve for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zoryve may be made for members who meet the following criteria:

**Age 12 Years and Above**

- Medical record documentation that Zoryve is prescribed by or in consultation with a dermatologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of chronic plaque psoriasis **AND**
- Medical record documentation of BSA involvement less than or equal to 20% **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to at least one of the following:
    - A high- to ultrahigh-potency TCS used concurrently with a generic topical calcipotriene product **OR**
    - A generic calcipotriene/betamethasone combination product **OR**
    - A high- to ultrahigh-potency TCS used concurrently with generic tazarotene 0.1%

**Age 6 to 11 Years**

- Medical record documentation that Zoryve is prescribed by or in consultation with a dermatologist or rheumatologist **AND**
- Medical record documentation of age 6 to 11 years **AND**
- Medical record documentation of a diagnosis of chronic plaque psoriasis **AND**
- Medical record documentation of BSA involvement less than or equal to 20% **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to a medium to high-potency topical corticosteroid used concurrently with a generic topical calcipotriene product [calcipotriene should be avoided on the face, genitalia, intertriginous areas/flexures]

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 60 grams (1 tube) every 30 days

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of the following:

- Medical record documentation of clinical improvement based on signs and symptoms of plaque psoriasis

If an exception is made, Zoryve will be paid for under the member's prescription drug benefit.

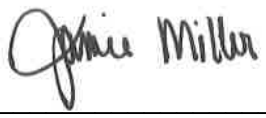
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

calcipotriene, calcipotriene-betamethasone, tazarotene, betamethasone, betamethasone-dipropionate, clobetasol, halobetasol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 1/20/23
Revised: 3/1/23 – annual review; updated signature

Geisinger

**POLICY NUMBER: 744.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zoryve**

Reviewed: 3/1/24 – annual review
Revised: 4/10/24 – added criteria for 6-11 year olds

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 745.0**

**SECTION: Commercial Drug**
**SUBJECT: Krazati**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Krazati for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Krazati may be made for members who meet the following criteria:

- Medical record documentation that Krazati is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a KRAS-G12C mutation, as determined by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of at least one prior systemic therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Krazati is configured as a prior authorization for new starts only. Krazati will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Krazati will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

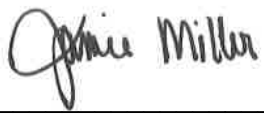
**FORMULARY ALTERNATIVES:**

Lumakras*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 3/1/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 746.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Aspruzyo Sprinkle**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aspruzyo Sprinkle for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Aspruzyo Sprinkle may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic angina **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ranolazine ER tablets **OR** documentation that member is unable to swallow tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 packets per day

If an exception is made, Aspruzyo Sprinkle will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

ranolazine ER tablets

| Geisinger | POLICY NUMBER: 746.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Aspruzyo Sprinkle |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 747.0**

**SECTION: Commercial Drug**
**SUBJECT: Auvelity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Auvelity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Auvelity may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure or intolerance to at least three antidepressant classes

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

If an exception is made, Auvelity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 747.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Auvelity |

**FORMULARY ALTERNATIVES:**

SSRIs: citalopram, fluoxetine, paroxetine, sertraline, escitalopram
MAOIs: phenelzine, tranylcypromine
SNRIs: venlafaxine hcl, venlafaxine er, duloxetine, desvenlafaxine ER (generic Pristiq)
Tricyclics: amitriptyline, nortriptyline, desipramine, doxepin, imipramine
Bupropion: bupropion hcl, bupropion xl, bupropion sr
Other: trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 748.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Jaypirca**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jaypirca for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Jaypirca may be made for members who meet the following criteria:

**Mantle Cell Lymphoma (MCL)**

- Medical record documentation that Jaypirca is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of mantle cell lymphoma (MCL) **AND**
- Medical record documentation of at least two lines of systemic therapy, including a BTK inhibitor

**Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**

- Medical record documentation that Jaypirca is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **AND**
- Medical record documentation of at least two lines of systemic therapy, including a BTK inhibitor and a BCL-2 inhibitor

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for 1 month duration

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg tablets: 1 tablet per day, 30 day supply per fill
  - 100 mg tablets: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Jaypirca is configured as a prior authorization for new starts only. Jaypirca will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Jaypirca will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

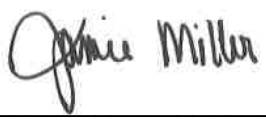
**FORMULARY ALTERNATIVES:**

BTK Inhibitors: Imbruvica*, Calquence*, Brukinsa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

| Geisinger | POLICY NUMBER: 748.0 |
| --- | --- |
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Jaypirca** |

Devised: 4/7/23
Reviewed: 3/1/24 – annual review
Revised: 4/10/24 – added CLL/SLL indications; updated MediSpan authorization level to 1 month auth

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 749.0**

**SECTION: Commercial Drug**
**SUBJECT: Orserdu**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orserdu for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Orserdu may be made for members who meet the following criteria:

- Medical record documentation that Orserdu is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of estrogen receptor (ER)-positive, HER2-negative (HER2-), ESR1-mutated advanced or metastatic breast cancer **AND**
- Medical record documentation that member is a postmenopausal female **OR** male **AND**
- Medical record documentation of disease progression following at least one prior endocrine therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 86 mg tablets: 3 tablets per day, 30 day supply per fill
  - 345 mg tablets: 1 tablet per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Orserdu is configured as a prior authorization for new starts only. Orserdu will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Orserdu will be paid for under the member's prescription drug benefit.

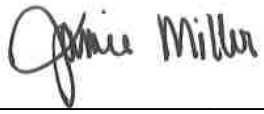
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Revised: 6/5/23 – removed reference to Jaypirca
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 750.0**

**SECTION: Commercial Drug**
**SUBJECT: Relyvrio**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Relyvrio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Relyvrio may be made for members who meet the following criteria:

- Medical record documentation that Relyvrio is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:**

- Initial Approval: *Quantity limit must be entered within authorization.*
  - In PA Hub: Add PA only for the approved authorization duration.
  - In Darwin: Add OQL and DS only, max number of claims authorized 1, max quantity dispensed 35, min day supply 28, max day supply 28, with a duration of one month.
    - QL FOR LETTER: Titration dose: 35 packets per 28 days; Maintenance dose: 56 packets per 28 days
- Renewals Requests: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
  - QL FOR LETTER ONLY: 56 packets per 28 days

**RE-AUTHORIZATION CRITERIA:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation that member is tolerating and compliant with prescribed Relyvrio regimen **AND**
- Medical record documentation of regular physician follow-up

If an exception is made, Relyvrio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

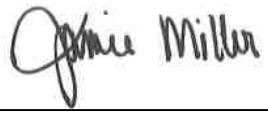
**FORMULARY ALTERNATIVES:**

riluzole, Radicava ORS*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Revised: 7/25/23 – corrected typos
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 751.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Tosymra** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tosymra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tosymra may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tosymra is being used for the acute treatment of migraines with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary triptans, one of which much be generic sumatriptan nasal spray

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 16 doses per 28 days (Dose limit applies across all oral triptan products.)

If an exception is made, Tosymra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

naratriptan, rizatriptan, sumatriptan, zolmitriptan

| Geisinger | POLICY NUMBER: 751.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tosymra |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 752.0**

**SECTION: Commercial Drug**
**SUBJECT: Tyvaso DPI**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tyvaso DPI for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tyvaso DPI may be made for members who meet the following criteria:

**Class III of IV Pulmonary Arterial Hypertension**

- Medical record documentation that Tyvaso DPI is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class III or IV pulmonary arterial hypertension **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with sildenafil **OR** bosentan

**Pulmonary Hypertension associated with Interstitial Lung Disease**

- Medical record documentation that Tyvaso DPI is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of pulmonary hypertension associated with interstitial lung disease (World Health Organization Group 3 Pulmonary Hypertension)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 16 mcg, 32 mcg, 48 mcg, and 64 mcg maintenance kit: 112 cartridges per 28 days
  - 32 and 48 mcg maintenance kit: 224 cartridges per 28 days
  - 16 and 32 mcg titration kit: 196 cartridges per 28 days
  - 16, 32, and 48 mcg titration kit: 252 cartridges per 28 days

If an exception is made, Tyvaso DPI will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

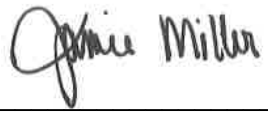
**FORMULARY ALTERNATIVES:**

sildenafil*, Liqrev*, bosentan*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 753.0**

**SECTION: Commercial Drug**
**SUBJECT: Non-Preferred Alternative Administration Proton Pump Inhibitors**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for esomeprazole packets, Nexium Packets, pantoprazole packets, Prilosec Packets, rabeprazole sprinkle capsules, Konvomep, and omeprazole/sodium bicarbonate packets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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3. ***Devised*** – the date the policy was implemented.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of esomeprazole packets, Nexium Packets, pantoprazole packets, Prilosec Packets, rabeprazole sprinkle capsules, Konvomep, or omeprazole/sodium bicarbonate packets may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lansoprazole orally dissolving tablets (ODT) **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that member has difficulty swallowing or has a nasogastric tube (NG) tube **OR**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two generic formulary alternatives (omeprazole capsules, pantoprazole tablets, lansoprazole capsules, esomeprazole capsules, rabeprazole tablets, or omeprazole/sodium bicarbonate capsules), one of which must contain the same active ingredient as the product requested, if available

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only if request is for esomeprazole packets, pantoprazole packets, rabeprazole sprinkle capsules, or omeprazole/sodium bicarbonate

If an exception is made, esomeprazole packets, Nexium Packets, pantoprazole packets, Prilosec Packets, rabeprazole sprinkle capsules, Konvomep, or omeprazole/sodium bicarbonate packets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

lansoprazole orally dissolving tablets, omeprazole capsules, pantoprazole tablets, lansoprazole capsules, esomeprazole capsules, rabeprazole tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Revised: 7/25/23 – added omeprazole/sodium bicarbonate packets to policy
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 754.0**

**SECTION: Commercial Drug**
**SUBJECT: Tezspire**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tezspire for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Tezspire may be made for members who meet the following criteria:

- Medical record documentation that Tezspire is prescriber by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of severe asthma **AND**
- Medical record documentation that Tezspire will be used as an add-on maintenance treatment **AND**
- Medical record documentation that Tezspire will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair, Nucala, Fasenra, Dupixent, Cinqair) **AND**
- Medical record documentation of one of the following:
    - Poor control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists) with or without oral corticosteroids **OR**
    - Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months despite current therapy to medium- high inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
    - 1.91 mL (210 mg) per 28 days

| Geisinger | POLICY NUMBER: 754.0 |
|---|---|
| POLICY AND PROCEDURE<br>PHARMACY<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tezspire |

**AUTHORIZATION DURATION:** Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences toxicity or worsening of disease.

If an exception is made, Tezspire will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, fluticasone diskus/HFA, Pulmicort Flexhaler, QVAR RediHaler, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 4/7/23
Revised: 6/5/23 – added auth duration
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 755.0**

**SECTION: Commercial Drug**
**SUBJECT: Ortikos**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ortikos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ortikos may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 8 years **AND**
- Medical record documentation of a diagnosis of mild to moderate Crohn's disease **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to at least three formulary alternatives, one of which is budesonide 3 mg oral capsule delayed release particles

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 1 capsule per day

If an exception is made, Ortikos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

budesonide 3 mg oral capsule delayed release particles, sulfasalazine 500 mg oral tablet, 500 mg DR oral tablet, prednisone 10 or 20 mg tablet or prednisolone 10mg/5ml, 15mg/5ml, or 25mg/5ml solution

| Geisinger | POLICY NUMBER: 755.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ortikos |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 756.0**

**SECTION: Commercial Drug**
**SUBJECT: Rezlidhia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rezlidhia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Rezlidhia may be made for members who meet the following criteria:

- Medical record documentation that Rezlidhia is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA) approved test*

***NOTE:** The FDA approved companion diagnostic test for Rezlidhia is Abbott RealTime IDH1.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Rezlidhia is configured as a prior authorization for new starts only. Rezlidhia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Rezlidhia will be paid for under the member's prescription drug benefit.

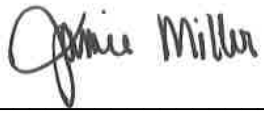
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 757.0**

**SECTION: Commercial Drug**
**SUBJECT: Cayston Inhalation Solution**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cayston Inhalation Solution for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Cayston Inhalation Solution may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that Cayston Inhalation Solution is prescribed by a pulmonologist or infectious disease specialist **AND**
- Medical record documentation of age greater than or equal to 7 years **AND**
- Medical record documentation that pseudomonas aeruginosa is positive in sputum, mouth swab or other cultures of the airway **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the use of tobramycin inhalation solution

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 84 vials per 56 days

If an exception is made, Cayston Inhalation Solution will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

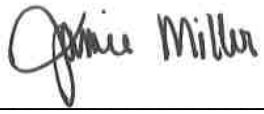
| Geisinger | POLICY NUMBER: 757.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Cayston Inhalation Solution |

**FORMULARY ALTERNATIVES:**
tobramycin inhalation solution*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY NUMBER: 758.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Hyftor**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Hyftor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Hyftor may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of facial angiofibroma associated with tuberous sclerosis **AND**
- Medical record documentation of age appropriate dosing (less than or equal to 600 mg per day for patients 6 to 11 years of age **OR** less than or equal to 800 mg per day for patients 12 years of age and older)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tubes (30 grams) per 30 days

**AUTHORIZATION DURATION:** Initial approval will be for 3 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of clinical improvement or lack of progression in symptoms of facial angiofibromas on Hyftor therapy.

If an exception is made, Hyftor will be paid for under the member's prescription drug benefit.

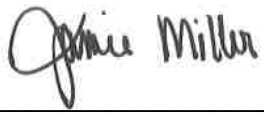
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 758.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Hyftor |

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 759.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Rayaldee**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rayaldee for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Rayaldee may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of secondary hyperparathyroidism **AND**
- Medical record documentation of stage 3 or stage 4 chronic kidney disease (CKD) **AND**
- Medical record documentation that member is not on dialysis **AND**
- Medical record documentation of serum total 25-hydroxyvitamin D levels less than 30 ng/mL **AND**
- Medical record documentation of serum calcium (corrected for low albumin) less than 9.8 mg/dL before starting treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) vitamin D supplement (cholecalciferol, ergocalciferol) **AND** one (1) vitamin D analog (calcitriol, doxercalciferol, paricalcitol)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 capsules per day

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require:

- Medical record documentation of a diagnosis of secondary hyperparathyroidism **AND**
- Medical record documentation of stage 3 or stage 4 chronic kidney disease (CKD) **AND**

- Medical record documentation that member is not on dialysis **AND**
- Medical record documentation that intact parathyroid hormone (PTH) is not consistently and abnormally low, serum calcium (corrected for low albumin) is not consistently above normal range, and 25-hydroxyvitamin D is not consistently greater than 100 ng/mL

If an exception is made, Rayaldee will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
ergocalciferol, calcitriol, doxercalciferol, paricalcitol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 760.0**

**SECTION: Commercial Drug**
**SUBJECT: Tascenso ODT**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tascenso ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Tascenso ODT may be made for members who meet the following criteria:

- Medical record documentation that the prescribed dose is appropriate for members age and weight **AND**
- Medical record documentation of trouble swallowing **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to fingolimod capsules (generic Gilenya)

**NOTE:** 0.25 mg strength is indicated for those greater than or equal to 10 years of age with a weight less than or equal to 40 kilograms.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

If an exception is made, Tascenso ODT will be paid for under the member's prescription drug benefit.

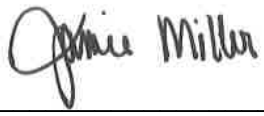
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 760.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Tascenso ODT |

**FORMULARY ALTERNATIVES:**
fingolimod (generic Gilenya) 0.5 mg capsules, Gilenya 0.25 mg capsules

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 761.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Vivjoa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vivjoa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vivjoa may be made for members who meet the following criteria:

- Medical record documentation of history of recurrent vulvovaginal candidiasis (RVVC) (greater than 3 acute vulvovaginal candidiasis episodes within 12 months) **AND**
- Medical record documentation of one of the following
  - Medical record documentation that member is postmenopausal **OR**
  - Medical record documentation that member is 12 years of age or older **AND** both of the following:
    - Medical record documentation that member is post-menarchal **AND**
    - Medical record documentation that member is not of reproductive potential (history of tubal ligation, salpingo-oophorectomy, or hysterectomy)
- Medical record documentation of therapeutic failure, contraindication, or intolerance to oral fluconazole tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, RX count 1

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 18 capsules per 84 days

If an exception is made, Vivjoa will be paid for under the member's prescription drug benefit.

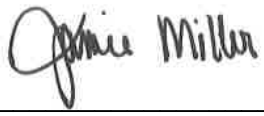
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 761.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Vivjoa |

**FORMULARY ALTERNATIVES:**
oral fluconazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 762.0**

**SECTION: Commercial Drug**
**SUBJECT: Xaciato**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xaciato for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xaciato may be made for members who meet the following criteria:

- Medical record documentation of bacterial vaginosis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be clindamycin 2% vaginal cream

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, RX count 1

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 5 grams (1 tube) per 30 days

If an exception is made, Xaciato will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

metronidazole tablets, metronidazole vaginal gel, clindamycin vaginal cream, Clindesse vaginal cream, Cleocin vaginal suppositories, tinidazole

| Geisinger | POLICY NUMBER: 762.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xaciato |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 6/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 763.0**

**SECTION: Commercial Drug**
**SUBJECT: Arikayce**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Arikayce for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Arikayce may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Arikayce is prescribed by a pulmonologist, infectious disease specialist, or *Mycobacterium avium* complex (MAC) lung disease specialist **AND**
- Medical record documentation of a diagnosis of Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture **AND**
- Medical record documentation that the patient has **NOT** achieved negative sputum cultures after a minimum of 6 consecutive months of receiving a multidrug background regimen containing at least 2 to 3 of the following agents:
    - Macrolide antibiotic [e.g., azithromycin, clarithromycin]
        - If macrolide-resistant [clofazimine]
    - Rifamycin antibiotic [e.g., rifampin, rifabutin]
    - Ethambutol **AND**
- Medical record documentation that Arikayce will be used in conjunction with a multidrug background regimen, including 2 to 3 of the following agents:
    - Macrolide antibiotic [e.g., azithromycin, clarithromycin]
        - If macrolide-resistant [clofazimine]
    - Rifamycin antibiotic [e.g., rifampin, rifabutin]
    - Ethambutol

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 vial per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Reauthorization will be for an additional 12 months and will require the following:

- Medical record documentation that Arikayce is prescribed by a pulmonologist, infectious disease specialist, or *Mycobacterium avium* complex (MAC) lung disease specialist **AND**
- Medical record documentation that Arikayce will continue to be used in conjunction with a multidrug background regimen, including 2 to 3 of the following agents:
    - Macrolide antibiotic [e.g., azithromycin, clarithromycin]
        - If macrolide-resistant [clofazimine]
    - Rifamycin antibiotic [e.g., rifampin, rifabutin]
    - Ethambutol **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that patient has achieved a negative sputum culture for *Mycobacterium avium* complex (MAC) in last 6 months

    **OR**
    - Medical record documentation that patient has **NOT** achieved a negative sputum culture for *Mycobacterium avium* complex (MAC) **AND**
    - Medical documentation of physician attestation that the member has demonstrated clinical benefit while on Arikayce

If an exception is made, Arikayce will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

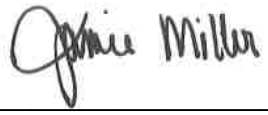
**FORMULARY ALTERNATIVES:**

azithromycin, clarithromycin, clofazimine, rifampin, rifabutin, ethambutol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 763.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Arikayce** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 764.0**

**SECTION: Commercial Drug**
**SUBJECT: Atorvaliq**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Atorvaliq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Atorvaliq may be made for members who meet the following criteria:

- Medical record documentation of an age greater than or equal to 10 years **AND**
- Medical record documentation of inability to tolerate or swallow tablets **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to up to three (3) preferred formulary statins of the same prescribed intensity*, one of which must be atorvastatin tablets

*High-, Moderate-, and Low-Intensity Statin Therapy

| | High Intensity | Moderate Intensity | Low Intensity |
|---|---|---|---|
| LDL-C lowering | ≥50% | 30%–49% | <30% |
| Statins | Atorvastatin 40 mg, 80 mg<br>Rosuvastatin 20 mg, 40 mg | Atorvastatin 10 mg, 20 mg<br>Rosuvastatin 5 mg, 10 mg<br>Simvastatin 20–40 mg | Simvastatin 10 mg |
| | | Pravastatin 40 mg, 80 mg<br>Lovastatin 40 mg, 80 mg<br>Fluvastatin XL 80 mg<br>Fluvastatin 40 mg BID<br>Pitavastatin 1–4 mg | Pravastatin 10–20 mg<br>Lovastatin 20 mg<br>Fluvastatin 20–40 mg |

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 20 mL per day

If an exception is made, Atorvaliq will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 764.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Atorvaliq |

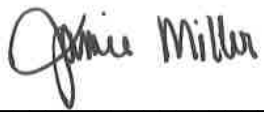
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

atorvastatin tablets, rosuvastatin tablets, simvastatin tablets, pravastatin tablets, lovastatin tablets, fluvastatin tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 765.0**

**SECTION: Commercial Drug**
**SUBJECT: Daybue**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Daybue for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Daybue may be made for members who meet the following criteria:

- Medical record documentation that Daybue is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of the *MECP2* gene **AND**
- Medical record documentation of diagnosis of classic, or typical Rett Syndrome* **AND**
- Medical record documentation of a member's baseline symptoms using an appropriate rating scale (e.g., Rett syndrome behaviour questionnaire, simplified severity score, Clinical Global Impression-Improvement assessment) **AND**
- Medical record documentation that Daybue is appropriately dosed

***NOTE:** Below outlines diagnosis of classic, or typical Rett Syndrome

1. A period of regression followed by recovery or stabilization **AND**
2. ALL of the following
    a. Partial or complete loss of acquired purposeful hand skills
    b. Partial or complete loss of acquired spoken language
    c. Gait abnormalities: Impaired (dyspraxic) or absence of ability
    d. Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms **AND**
3. NONE of the following
    a. Brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection that causes neurologic problems
    b. Grossly abnormal psychomotor development in the first six months of life

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 120 mL per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 3 months or less if the provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in Rett syndrome symptoms as measured by an appropriate rating scale (compared to previous measurement)

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the follow criteria is required.

- Medical record documentation of clinical improvement in Rett syndrome symptoms as measured by an appropriate rating scale (compared to previous measurement)

If an exception is made, Daybue will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

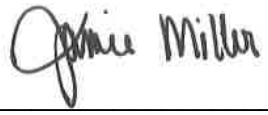
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 765.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Daybue |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 766.0**

**SECTION: Commercial Drug**
**SUBJECT: Filspari**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Filspari for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Filspari may be made for members who meet the following criteria:

- Medical record documentation of primary immunoglobulin A nephropathy (IgAN) verified by biopsy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Filspari is prescribed by or in consultation with a nephrologist **AND**
- Medical record documentation that member is at high risk of disease progression, defined as urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g or proteinuria greater than or equal to 1 g/day **AND**
- Medical record documentation that member has received greater than or equal to 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification **AND**
- Medical record documentation of estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 $m^2$ **AND**
- Medical record documentation that member has received a stable dose of a renin-angiotensin system (RAS) inhibitor (angiotensin-converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]) at a maximally tolerated dose for greater than or equal to 90 days **AND**
- Medical record documentation that (RAS) inhibitor (angiotensin-converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]) will be discontinued prior to initiation of treatment with Filspari **AND**
- Medical record documentation that Filspari will NOT be used in combination with any (RAS) inhibitors (angiotensin-converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), endothelin receptor antagonists, or aliskiren

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for nine (9) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued disease improvement or lack of disease progression according to prescriber (i.e., decreased levels of proteinuria from baseline or decreased urine protein-to-creatinine ratio (UPCR) from baseline) **AND**
- Medical record documentation that Filspari will NOT be used in combination with any (RAS) inhibitors (angiotensin-converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), endothelin receptor antagonists, or aliskiren

If an exception is made, Filspari will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

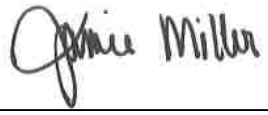
**FORMULARY ALTERNATIVES:**

**ARB:** candesartan, losartan, irbesartan, olmesartan, telmisartan, valsartan
**ARB/diuretic combinations:** candesartan/hctz, irbesartan/hctz, losartan/hctz, olmesartan/hctz, telmisartan/hctz, valsartan/hctz
**ACE inhibitors:** benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, trandolapril, ramipril
**ACE inhibitors/diuretic combinations:** captopril/hctz, benazepril/hctz, enalapril/hctz, lisinopril/hctz, moexipril/hctz

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 766.0 |
| --- | --- |
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Filspari |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 767.0**

**SECTION: Commercial Drug**
**SUBJECT: Skyclarys**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Skyclarys for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Skyclarys may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation that Skyclarys is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of Friedrich's Ataxia **AND**
- Medical record documentation of genetic testing confirming Frataxin (FXN) gene mutation **AND**
- Medical record documentation of baseline modified Friedreich's Ataxia Rating Scale (mFARS) score

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require:

- Medical record documentation that the member is responding positively to therapy as evidenced by slowed disease progression or documentation of a positive clinical response (ex. through mFARS-modified functional assessment rating scale)

If an exception is made, Skyclarys will be paid for under the member's prescription drug benefit.

| Geisinger | POLICY NUMBER: 767.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Skyclarys |

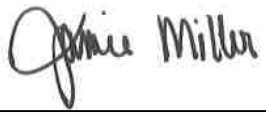
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 7/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 768.0**

**SECTION: Commercial Drug**
**SUBJECT: Cuvrior**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cuvrior for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Cuvrior may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Wilson's disease **AND**
- Medical record documentation of controlled Wilson's disease as evident by serum non-ceruloplasmin copper (NCC) level between greater than or equal to 25 and less than or equal to 150 mcg/L **AND**
- Medical record documentation that the member is tolerant to penicillamine and that penicillamine will be discontinued prior to therapy with Cuvrior **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to trientine

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 tablets per day, 28 day supply per fill

If an exception is made, Cuvrior will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

trientine capsules, penicillamine capsules

| Geisinger | POLICY NUMBER: 768.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Cuvrior |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/5/23
Revised: 3/1/24 – annual review; removed references to Filspari

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 769.0**

**SECTION: Commercial Drug**
**SUBJECT: Penicillamine Tablets**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for penicillamine tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of penicillamine tablets may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to penicillamine capsules

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, generic only

If an exception is made, penicillamine tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

penicillamine capsules

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

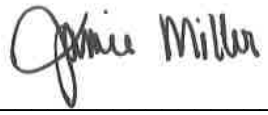
**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 769.0**

**SECTION: Commercial Drug**
**SUBJECT: Penicillamine Tablets**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/5/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 770.0**

**SECTION: Commercial Drug**
**SUBJECT: Furoscix**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Furoscix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Furoscix may be made for members who meet the following criteria:

- Medical record documentation that Furoscix is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of New York Heart Association (NYHA) Class II or Class III chronic heart failure **AND**
- Medical record documentation of congestion due to fluid overload **AND**
- Medical record documentation that member is stable on background loop diuretic therapy **AND**
- Medical record documentation of provider attestation that member will use Furoscix for short-term use only and will be transitioned to oral diuretics as soon as practical

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**AUTHORIZATION DURATION:** 1 month

If an exception is made, Furoscix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 770.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Furoscix |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY NUMBER: 771.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Inpefa**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inpefa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Inpefa may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
  - Medical record documentation of a diagnosis of heart failure **OR**
  - Medical record documentation of a diagnosis of type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), or other cardiovascular (CV) risk factors **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance **AND** Farxiga

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Inpefa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

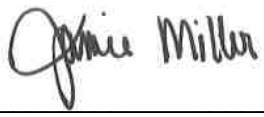
**FORMULARY ALTERNATIVES:**

Jardiance, Synjardy, Farxiga, Xigduo

| Geisinger | POLICY NUMBER: 771.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Inpefa |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 772.0**

**SECTION: Commercial Drug**
**SUBJECT: Joenja**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Joenja for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Joenja may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) **AND**
- Medical record documentation of weight greater than or equal to 45 kilograms **AND**
- Medical record documentation of a mutation in *PIK3CD* **OR** *PIK3R1* gene

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and ill require medical record documentation of clinical improvement or lack of progression in symptoms of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) on Joenja therapy.

If an exception is made, Joenja will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

| Geisinger | POLICY NUMBER: 772.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Joenja |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 773.0**

**SECTION: Commercial Drug**
**SUBJECT: Lumryz**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lumryz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Lumryz may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil, methylphenidate immediate release **OR** amphetamine/dextroamphetamine immediate release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 9 grams per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

If an exception is made, Lumryz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

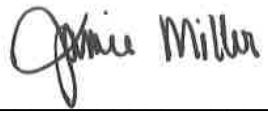
**FORMULARY ALTERNATIVES:**

modafinil*, methylphenidate immediate release, amphetamine/dextroamphetamine immediate release

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 774.0**

**SECTION: Commercial Drug**
**SUBJECT: Veozah**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Veozah for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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**ADDITIONAL DEFINITIONS:**

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2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Veozah may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of menopause with moderate to severe vasomotor symptoms (VMS) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) different medications from at least two (2) of the following categories:
    - Estrogens
    - Non-Hormonal Agents

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Veozah will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 774.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Veozah |

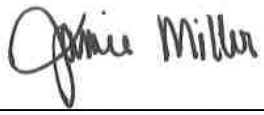
**FORMULARY ALTERNATIVES:**

Hormonal: estradiol tab/patch, estradiol vaginal cream estradiol norethindrone acetate, norethindrone acetate/ethinyl estradiol, Fyavolv Tablet, medroxyprogesterone, Premarin cream/tablet, Premphase, Prempro, Yuvafem Vaginal Tablet

Non-Hormonal: paroxetine, citalopram, escitalopram, venlafaxine tablet, venlafaxine ER, desvenlafaxine, gabapentin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 775.0**

**SECTION: Commercial Drug**
**SUBJECT: Vowst**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vowst for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Vowst may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vowst is prescribed by or in consultation with an infectious disease specialist or gastroenterologist **AND**
- Medical record documentation that Vowst will be used for the prevention of recurrence of clostridium difficile infections **AND**
- Medical record documentation of a diagnosis of recurrent clostridium difficile infection based on the results of an appropriate laboratory stool test within 30 days of prior authorization request **AND**
- Medical record documentation that an appropriate standard-of-care antibacterial regimen was used for the treatment of recurrent clostridium difficile infection (for example, oral fidaxomicin, oral vancomycin, oral metronidazole) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Rebyota

**NOTE:** Vowst is not indicated for the treatment of clostridium difficile infections. There is no information currently available indicating that an individual is unable to receive more than one treatment course of Vowst.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 12 capsules per 30 days

| Geisinger | POLICY NUMBER: 775.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Vowst |

**AUTHORIZATION DURATION:** 30 days

If an exception is made, Vowst will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

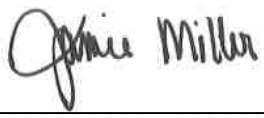
**FORMULARY ALTERNATIVES:**

Rebyota (medical benefit)*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Revised: 3/1/24 – annual review; corrected typo

Geisinger

**POLICY NUMBER: 776.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Zonisade**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zonisade for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Zonisade may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation of a diagnosis of epilepsy **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to zonisamide capsules **OR**
  - Medical record documentation of the inability to tolerate or swallow capsules **AND**
- If requested dose exceeds 400 mg per day:
  - Medical record documentation of therapeutic failure of 400 mg dose **AND**
  - Adequate medical and scientific evidence in the medical literature to support doses above 400 mg per day

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 30 mL per day

If an exception is made, Zonisade will be paid for under the member's prescription drug benefit.

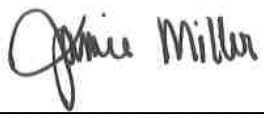
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

zonisamide capsules

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Revised: 2/12/24 – added continuity of care language
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 777.0**

**SECTION: Commercial Drug**
**SUBJECT: Saxenda**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Saxenda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Pharmaceuticals for chronic weight management are not covered, except for certain clients that request this benefit.

An exception for coverage of Saxenda may be made for members who meet the following criteria:

- Medical record documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Saxenda **AND**
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of age greater than or equal to 18 years with one of the following:
        - Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/$m^2$ **OR**
        - Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/$m^2$ and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) **AND**
    - Medical documentation of age greater than or equal to 12 years and less than 18 years with body weight above 60 kg and an initial body mass index (BMI) corresponding to 30 kg/m2 for adults by international cut-offs (Cole Criteria) **AND**
- Medical documentation of therapeutic failure to Wegovy

**NOTE:** Saxenda is not indicated for treatment of chronic weight management:

- In combination with liraglutide containing products or any other GLP-1 receptor agonist
- In combination with other products for weight loss, as safety and efficacy or coadministration has not been established
- In pediatric patients with type 2 diabetes
- In patients with acute pancreatitis. Caution in patients with history of pancreatitis.
- In patients with personal or family history of medullary thyroid C-cell carcinoma or Multiple Endocrine Neoplasia syndrome type 2
- In known hypersensitivity to liraglutide or any of the excipients
- In pregnancy

**MEDISPAN APPROVAL LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation that the member continues to experience clinical benefit from Saxenda based on the prescriber's assessment **AND**
- Medical record documentation that member has experienced at least a 4% reduction in weight from baseline.

If an exception is made, Saxenda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

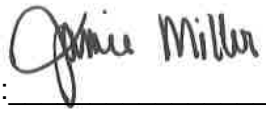
Wegovy*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 777.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Saxenda** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/6/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 778.0**

**SECTION: Commercial Drug**
**SUBJECT: Xenical**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xenical for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Pharmaceuticals for chronic weight management are not covered, except for certain clients that request this benefit.

An exception for coverage of Xenical may be made for members who meet the following criteria:

**Chronic Weight Management**

- Medical record documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Xenical **AND**
- Medical record documentation of use in conjunction with reduced calorie diet for chronic weight management **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of body mass index (BMI) greater than or equal to 30 $kg/m^2$ **OR**
    - Medical record documentation of body mass index (BMI) greater than or equal to 27 $kg/m^2$ and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) **AND**
- Medical documentation of therapeutic failure to Wegovy

**Risk of Weight Regain**

- Medical documentation of use for reduced risk of weight regain after prior established weight loss

**NOTE:** Xenical is not indicated for treatment of chronic weight management:

- In patients with chronic malabsorption syndrome
- In patients with cholestasis
- In known hypersensitivity to orlistat or any of the excipients
- In pregnancy

**MEDISPAN APPROVAL LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation that the member continues to experience clinical benefit from Xenical based on the prescriber's assessment **AND**
- Medical record documentation that member has experienced at least a 4% reduction in weight from baseline.

If an exception is made, Xenical will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

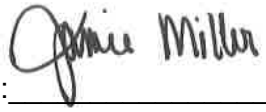
**FORMULARY ALTERNATIVES:**

Wegovy*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 778.0**

**SECTION: Commercial Drug**
**SUBJECT: Xenical**

Date: March 1, 2024

Devised: 10/25/23
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 779.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Contrave** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Contrave for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Pharmaceuticals for chronic weight management are not covered, except for certain clients that request this benefit.

An exception for coverage of Contrave may be made for members who meet the following criteria:

- Medical record documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Contrave **AND**
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of body mass index (BMI) greater than or equal to 30 $kg/m^2$ **OR**
    - Medical record documentation of body mass index (BMI) greater than or equal to 27 $kg/m^2$ and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) **AND**
- Medical documentation of therapeutic failure to Wegovy

**NOTE:** Contrave is not indicated for treatment of chronic weight management:

- In patients with major depressive disorder or other psychiatric disorders due to increased risk of suicidal thinking and behavior
- In combination with bupropion containing products
- In combination with other products for weight loss, as safety and efficacy or coadministration has not been established
- In uncontrolled hypertension

- In patients with seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- In combination with chronic opioid use
- In concomitant use or within 14 days of taking monoamine oxidase inhibitors (MAOI)
- In known hypersensitivity to any ingredients of naltrexone/bupropion
- In pregnancy
- In pediatric patients

**MEDISPAN APPROVAL LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation that the member continues to experience clinical benefit from Contrave based on the prescriber's assessment **AND**
- Medical record documentation that member has experienced at least a 4% reduction in weight from baseline.

If an exception is made, Contrave will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Wegovy*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 779.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Contrave** |

Signed:_____

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 780.0**

**SECTION: Commercial Drug**
**SUBJECT: Qsymia**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qsymia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.

5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

Pharmaceuticals for chronic weight management are not covered, except for certain clients that request this benefit.

An exception for coverage of Qsymia may be made for members who meet the following criteria:

**Adults**

- Medical record documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Qsymia **AND**
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of body mass index (BMI) greater than or equal to 30 $kg/m^2$ **OR**
    - Medical record documentation of body mass index (BMI) greater than or equal to 27 $kg/m^2$ and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) **AND**
- Medical documentation of therapeutic failure to Wegovy

**Pediatrics**

- Medical record documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex **AND**
- Medical documentation of therapeutic failure to Wegovy

**NOTE:** Qsymia is not indicated for treatment of chronic weight management:

- In pregnancy
- In combination with other products for weight loss, as safety and efficacy or coadministration has not been established
- In patients with glaucoma
- In patients with hyperthyroidism
- In concomitant use or within 14 days of taking monoamine oxidase inhibitors (MAOI)
- In known hypersensitivity to any component of Qsymia or idiosyncrasy to sympathomimetic amines

**MEDISPAN APPROVAL LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation that the member continues to experience clinical benefit from Qsymia based on the prescriber's assessment **AND**
- Medical record documentation that member has experienced at least a 3% reduction in weight from baseline.

If an exception is made, Qsymia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

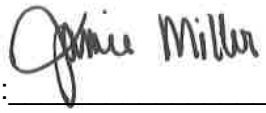
Wegovy*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 780.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Qsymia** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 781.0**

**SECTION: Commercial Drug**
**SUBJECT: Omnipod 5**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Omnipod 5 for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Omnipod 5 may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of type 1 diabetes mellitus

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

If an exception is made, Omnipod 5 will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

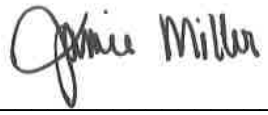
**FORMULARY ALTERNATIVES:**

Omnipod Dash

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 781.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Omnipod 5 |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 10/25/23
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 782.0**

**SECTION: Commercial Drug**
**SUBJECT: Victoza and Ozempic for Geisinger Employees**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | | Medicaid | |
| Medicare | | ACA | |
| GHP Kids | | Self-Insured | X |

*This policy is only applicable to Geisinger Employee Plan members.

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ozempic and Victoza for Geisinger Employee Plan members. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Ozempic or Victoza may be made for members who meet the following criteria:

**Ozempic or Victoza for Diabetes**

- Medical record documentation of a diagnosis of type II diabetes mellitus

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY:

- Victoza: 9 mL per 28 days
- Ozempic: 3 mL per 28 days

**Victoza for Weight Loss**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Victoza is managed by Geisinger Nutrition and Weight Management or Geisinger Endocrinology **AND**
- Medical record documentation of body mass index (BMI) greater than or equal to 30 $kg/m^2$ **AND**
- Medical record documentation of at least one of the following specific weight related comorbid conditions:
  - Hemoglobin A1C (HgbA1c) between 6% - 6.4%
  - Elevated aspartate aminotransferase (AST) or alanine transaminase (ALT)
  - Obstructive sleep apnea requiring treatment with CPAP/BiPAP

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: Victoza: 9 mL per 28 days

**Ozempic for Weight Loss**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ozempic is managed by Geisinger Nutrition and Weight Management or Geisinger Endocrinology **AND**
- Medical record documentation of body mass index (BMI) greater than or equal to 30 $kg/m^2$ **AND**
- Medical record documentation of at least one of the following specific weight related comorbid conditions:
  - Hemoglobin A1C (HgbA1c) between 6% - 6.4%
  - Elevated aspartate aminotransferase (AST) or alanine transaminase (ALT)
  - Obstructive sleep apnea requiring treatment with CPAP/BiPAP **AND**
- Medical record documentation of therapeutic failure of Victoza defined as failure to achieve a 10% weight loss after 6 months of Victoza therapy

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be indefinite. Reauthorization will require the following be met:

- Medical record documentation of 5% weight loss **AND**
- Medical record documentation that Ozempic is managed by Geisinger Nutrition and Weight Management or Geisinger Endocrinology

**MEDISPAN APPROVAL LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

QL FOR LETTER ONLY: Ozempic: 3 mL per 28 days

If an exception is made, Victoza or Ozempic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 782.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Victoza and Ozempic for Geisinger Employees |

**FORMULARY ALTERNATIVES:**

Request for Ozempic: Victoza*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jennie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 12/7/23
Reviewed: 3/1/24 – annual review
Revised: 4/10/24 – corrected typo in sleep apnea criterion

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 783.0**

**SECTION: Commercial Drug**
**SUBJECT: Akeega**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Akeega for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Akeega may be made for members who meet the following criteria:

- Medical record documentation that Akeega is prescribed by an oncologist or urologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of deleterious or suspected deleterious BRCA-mutation (BRCAm) as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Akeega will be given in combination with prednisone **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that Akeega will be given concurrently with a gonadotropin-releasing hormone (GnRH) **OR**
    - Medical record documentation that member has had bilateral orchiectomy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Akeega is configured as a prior authorization for new starts only. Akeega will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Akeega will be paid for under the member's prescription drug benefit.

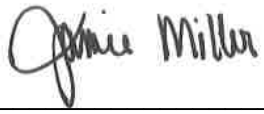
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 784.0**

**SECTION: Commercial Drug**
**SUBJECT: Brenzavvy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Brenzavvy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Brenzavvy may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type 2 diabetes mellitus (T2DM) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance **AND** Farxiga

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Brenzavvy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

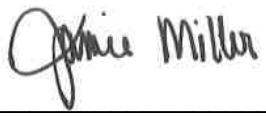
**FORMULARY ALTERNATIVES:**

Jardiance, Synjardy, Farxiga, Xigduo

| Geisinger | POLICY NUMBER: 784.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Brenzavvy |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Revised: 3/1/24 – annual review; updated FA

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 784.0**

**SECTION: Commercial Drug**
**SUBJECT: Olpruva**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Olpruva for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Olpruva may be made for members who meet the following criteria:

- Medical record documentation of use for urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) **AND**
- Medical record documentation of adjunctive therapy to a protein-restricted diet **AND**
- Medical record documentation of increased blood ammonia levels **AND**
- Medical record documentation of patient weighing 20 kilograms (kg) or greater and with a body surface area (BSA) of 1.2 $m^2$ or greater **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on sodium phenylbutyrate powder **AND** sodium phenylbutyrate tablets

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - For 2 gm dose: 20 packets per day (10, 2 gram dose envelopes per day), 30 day supply per fill
  - For 3 gm dose: 12 packets per day (6, 3 gram dose envelopes per day) , 30 day supply per fill
  - For 4 gm dose: 15 packets per day (5, 4 gram dose envelopes per day) , 30 day supply per fill
  - For 5 gm dose: 12 packets per day (4, 5 gram dose envelopes per day) , 30 day supply per fill
  - For 6 gm and 6.67gm dose: 9 packets per day (3, 6 gram or 6.67 gram dose envelopes per day), 30 day supply per fill

| Geisinger | POLICY NUMBER: 784.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Olpruva** |

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of improvement in either fasting ammonia levels, 24 hour AUC, or number of hyperammonemic crises

If an exception is made, Olpruva will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

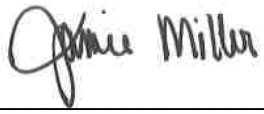
**FORMULARY ALTERNATIVES:**

sodium phenylbutyrate powder*, sodium phenylbutyrate tablet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 786.0**

**SECTION: Commercial Drug**
**SUBJECT: Vanflyta**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vanflyta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Vanflyta may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vanflyta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of newly diagnosed acute myeloid leukemia (AML) **AND**
- Medical record documentation that member is FLT3 internal tandem duplication (ITD)-positive as detected by a Food and Drug Administration (FDA)-approved test* **AND**
- Medical record documentation that Vanflyta will be used in combination with standard cytarabine and anthracycline induction, in combination with cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy (excludes maintenance monotherapy following allogeneic hematopoietic stem cell transplantation)

**NOTE:** The FDA-approved test for FLT3-ITD positive AML is LeukoStrat CDx FLT3 Mutation Assay

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Initial approval will be for 6 months. Subsequent approvals will be for 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Vanflyta for the treatment of FLT3-ITD positive acute myeloid leukemia (AML) should not exceed the FDA-approved treatment duration of 2 cycles of induction, up to 4 cycles of consolidation, and up to 36 cycles as maintenance. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

If an exception is made, Vanflyta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

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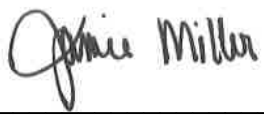
Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24

Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 787.0**

**SECTION: Commercial Drug**
**SUBJECT: Zavzpret**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zavzpret for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Zavzpret may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Nurtec ODT and Ubrelvy **AND**
- Medical record documentation Zavzpret will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g., Nurtec ODT or Ubrelvy)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 actuations per 30 days

If an exception is made, Zavzpret will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Nurtec ODT*/**, Ubrelvy*/**

*prior authorization required, **quantity limits apply

| Geisinger | POLICY NUMBER: 787.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Zavzpret |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

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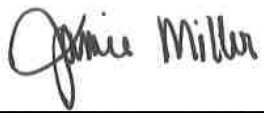
Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 788.0**

**SECTION: Commercial Drug**
**SUBJECT: Non-Preferred Adalimumab Biosimilars**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Abrilada, Amjevita, Cyltezo, Adalimumab-adbm (unbranded Cyltezo), Hulio, Hyrimoz, Adalimumab-adaz (unbranded Hyrimoz), Idacio, and Yuflyma for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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4. ***NCQA*** – National Committee for Quality Assurance.

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    A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
    C. In accordance with current standards of medical practice;
    D. Not primarily for the convenience of the Member, or the Member's Provider; and
    E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Abrilada, Amjevita, Cyltezo, Adalimumab-adbm (unbranded Cyltezo), Hulio, Hyrimoz, Adalimumab-adaz (unbranded Hyrimoz), Idacio, or Yuflyma may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure of, intolerance to, or contraindication to three of the following: Humira, Adalimumab-fkjp, Hadlima, or Yusimry

**MEDISPAN AUTHORIZATION LEVEL:** NDC-9

**QUANTITY LIMITS:**

- For Rheumatoid Arthritis:
    - Bi-Weekly Dosing:
        - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
        - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
            - QL for letter: 2 per 28 days
    - Weekly Dosing:
        - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
        - In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099
            - QL for letter: 4 per 28 days
- For PJIA/JA:
    - Bi-Weekly Dosing:
        - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
        - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
            - QL for letter: 2 per 28 days

- For Psoriatic Arthritis:
  - Bi-Weekly Dosing:
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
      - QL for letter: 2 per 28 days
- For AS:
  - Bi-Weekly Dosing:
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099
      - QL for letter: 2 per 28 days
- For Crohn's:
  - Adults and pediatrics > 40 kg: 160 mg on Day 1, 80 mg 2 weeks later, then 40 mg biweekly
    - In NCRX: Add PA, OQL, max quantity 6, max day supply 28, max script 1 for a 3 week authorization duration
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for Letter: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
  - Pediatrics < 40 kg: 80 mg on day 1, 40 mg 2 weeks later, then 20 mg biweekly
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for letter: Loading dose: 80 mg on day 1, 40 mg 2 weeks later; Maintenance dose: 20 mg every other week (2 pens/syringes per 28 days)
  - Weekly dosing:
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099
      - QL for Letter: 4 per 28 days
- For PP:
  - 80 mg on day 1, then 40 mg biweekly
    - In NCRX: Add PA, OQL, max quantity 4, max day supply 28, max script 1 for a 3 week authorization duration
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
      - QL for Letter: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)

- For UC:
  - Adults: 160 mg on Day 1, 80 mg 2 weeks later, then 40 mg biweekly
    - In NCRX: Add PA, OQL, max quantity 6, max day supply 28, max script 1 for a 3 week authorization duration
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for Letter: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
  - Adult Weekly dosing:
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099
      - QL for Letter: 4 per 28 days
  - Pediatrics 20 to 40 kg: 80 mg on day 1, 40 mg on day 8 and day 15, then 20 mg every week
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for letter: Loading dose: 80 mg on day 1, 40 mg on day 8 and day 15; Maintenance dose: 20 mg every week (4 pens/syringes per 28 days)
  - Pediatrics greater than 40 kg: 160 mg on day 1, 80 mg on day 8 and day 15, then 40 mg every week
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for letter: Loading dose: 160 mg on day 1, 80 mg on day 8 and day 15; Maintenance dose: 40 mg every week (4 pens/syringes per 28 days)
- For HS:
  - Adults and age 12-18 years weighing ≥ 60 kg: 160 mg on Day 1, 80 mg 2 weeks later, then 40 mg weekly
    - In NCRX: Add PA, OQL, max quantity 6, max day supply 28, max script 1 for a 3 week authorization duration
    - In PA Hub: Add OQL, max quantity dispensed 4, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for Letter: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every week (4 pens/syringes per 28 days)
  - Adults and age 12-18 years weighing ≥ 60 kg: 160 mg on Day 1, 80 mg 2 weeks later, then 80 mg biweekly
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
      - QL for Letter: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 80 mg every other week (2 pens/syringes per 28 days)

  - Age 12-18 years weighing 30 to < 60 kg: 80 mg on day 1, then 40 mg biweekly
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 2 with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
      - QL for Letter: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- For Panuveitis:
  - Adult: 80 mg on day 1, then 40 mg biweekly
    - In NCRX: Add PA, OQL, max quantity 4, max day supply 28, max script 1 for a 3 week authorization duration
    - In PA Hub: Add OQL, max quantity dispensed 2, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
      - QL for Letter: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
  - Pediatric:
    - In NCRX: Add PA, max script 1, enter for the remainder of the calendar year
    - In PA Hub: Add OQL, max quantity dispensed 2with an end date of 12/31/2099.
      - QL for letter: 2 per 28 days

If an exception is made, Abrilada, Amjevita, Cyltezo, Adalimumab-adbm (unbranded Cyltezo), Hulio, Hyrimoz, Adalimumab-adaz (unbranded Hyrimoz), Idacio, or Yuflyma will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

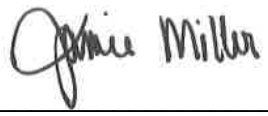
Humira*, Adalimumab-fkjp*, Hadlima*, Yusimry*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | **POLICY NUMBER: 788.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Non-Preferred Adalimumab Biosimilars** |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 789.0**

**SECTION: Commercial Drug**
**SUBJECT: Litfulo**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Litfulo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

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1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Litfulo may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of severe alopecia areata, defined as at least 50% scalp hair lose as measured by the Severity of Alopecia Tool (SALT) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one of the following:
    - Systemic therapy used for at least 3 months (for example, corticosteroids, methotrexate, cyclosporine) **OR**
    - Prescription topical corticosteroids used for at least 28 days **OR**
    - Intralesional corticosteroids used for at least 3 months **AND**
- Medical record documentation that member does not have hair loss due to androgenetic alopecia (includes male and female pattern hair loss), chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata **AND**
- Medical record documentation that Litfulo is not prescribed in combination with other Janus kinase inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical

improvement or lack of progression in signs and symptoms of alopecia areata on Litfulo therapy is required.

If an exception is made, Litfulo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

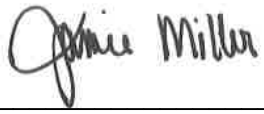
**FORMULARY ALTERNATIVES:**

prednisone, methylprednisolone, dexamethasone, prednisolone
**Low-potency topical corticosteroids:** alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
**High-potency topical corticosteroids:** amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam (Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP); ); diflorasone 0.05% cream (Florone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog)
**Very high-potency topical corticosteroids:** augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam (Temovate/Clobex/Olux); diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E); fluocinonide 0.1% cream (Vanos); halobetasol 0.05% cream and ointment (Ultravate)

| Geisinger | **POLICY NUMBER: 789.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Litfulo** |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Revised: 3/1/24 – annual review; corrected age to 12 years; added approval statement

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 790.0**

**SECTION: Commercial Drug**
**SUBJECT: Fruzaqla**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fruzaqla for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Fruzaqla may be made for members who meet the following criteria:

- Medical record documentation that Fruzaqla is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer (mCRC) **AND**
- Medical record documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 1 mg tablets: 3 tablets per day, 28 day supply per fill
  - 5 mg tablets: 21 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Fruzaqla is configured as a prior authorization for new starts only. Fruzaqla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Fruzaqla will be paid for under the member's prescription drug benefit.

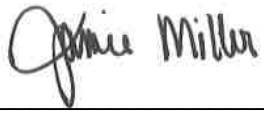
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 791.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Ojjaara** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ojjaara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Ojjaara may be made for members who meet the following criteria:

- Medical record documentation that Ojjaara is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count greater than or equal to 25 x $10^9$/L AND Medical record documentation of transfusion-dependent anemia associated with Myelofibrosis (not for patients with symptomatic splenomegaly only) **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of baseline total symptom score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Ojjaara will not be used concurrently with other kinase inhibitors.

**NOTE:** Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

- Age > 65 years
- WBC > 25 x $10^9$/L
- Hemoglobin < 10 g/dL

- Blood Blasts ≥ 1%
- Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- Transfusion dependency
- Platelets less than 100 X $10^9$/L
- Unfavorable karyotype

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Ojjaara will no longer be covered if medical record documentation does not show:

- Medical record documentation of platelet count greater than or equal to 25 x $10^9$/L **AND**
- The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

If an exception is made, Ojjaara will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

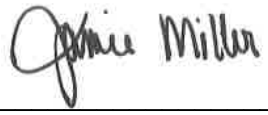
**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

| Geisinger | POLICY NUMBER: 791.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Ojjaara |

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 792.0**

**SECTION: Commercial Drug**
**SUBJECT: Sohonos**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sohonos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Sohonos may be made for members who meet the following criteria:

- Medical record documentation that Sohonos is prescribed by or in consultation with an endocrinologist or a physician who specializes in connective tissue or bone diseases **AND**
- Medical record documentation of a diagnosis of fibrodysplasia ossificans progressive (FOP) **AND**
- Medical record documentation of confirmed Activin A Type 1 Receptor (ACVR1) R206H mutation **AND**
- Medical record documentation of age greater than or equal to 8 years for females **OR** greater than equal to 10 years for males

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 1 mg tablets: 4 tablets per day, 30 day supply per fill
  - 1.5 mg tablets: 2 tablets per day, 30 day supply per fill
  - 2.5 mg tablets: 3 tablets per day, 30 day supply per fill
  - 10 mg tablets: 2 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

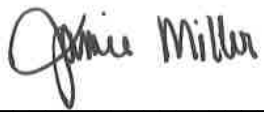
If an exception is made, Sohonos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 793.0**

**SECTION: Commercial Drug**
**SUBJECT: Truqap**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Truqap for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Truqap may be made for members who meet the following criteria:

- Medical record documentation that Truqap is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic breast cancer that is hormone receptor-positive, HER2-negative (HR+/HER2-) **AND**
- Medical record documentation of one or more PIK3CA, AKT1, or PTEN-alteration determined using a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation that Truqap is being prescribed in combination with fulvestrant **AND**
- Medical record documentation of one of the following:
    - Documentation of therapeutic failure on, intolerance to, or contraindication to prior endocrine therapy **OR**
    - Documentation of recurrence on or within 12 months of completing adjuvant therapy

**NOTE:** The FDA approved test is the *FoundationOneCDx.*

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 64 tablets per 28 days

**RE-AUTHORIZATION CRITERIA:** Truqap is configured as a prior authorization for new starts only. Truqap will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Truqap will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

Endocrine Therapy: exemestane, letrozole, anastrozole, tamoxifen, toremifene

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 794.0**

**SECTION: Commercial Drug**
**SUBJECT: Xdemvy**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xdemvy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xdemvy may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic *Demodex* blepharitis (DB) evidenced by:
  - Presence of at least mild erythema of the upper eyelid margin **AND**
  - Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination **AND**
- Medical record documentation that Xdemvy is prescribed by or in consultation with an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**NOTE:** The clinical trials performed evaluated a 6-week treatment course only. The benefits of a longer treatment course of Xdemvy are unknown. Tarsus has stated that retreatment may be necessary in about 40% of patients at 1 year following initial treatment, so while a longer treatment course is not advisable, retreatment in some patients is likely to be necessary.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 mL per 42 days

**AUTHORIZATION DURATION:** 6 weeks

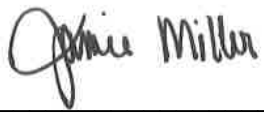
If an exception is made, Xdemvy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

| Geisinger | POLICY NUMBER: 795.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Zurzuvae** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zurzuvae for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Zurzuvae may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of postpartum depression (PPD) as defined by both of the following:
  - Medical record documentation that member is experiencing a major depressive episode **AND**
  - Medical record documentation that member experienced onset of symptoms within the third trimester or within 4 weeks of delivery **AND**
- Medical record documentation that member is less than or equal to 12 months postpartum **AND**
- Medical record documentation that the current depressive episode is moderate to severe based on a standardized and validated questionnaire/scale [e.g., a score of greater than 10 on the Patient Health Questionnaire (PHQ-9), a score of greater than 20 on the Hamilton Depression Rating Scale (HAM-D), etc.]

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 20 and 25 mg tablets: 2 tablets per day, 14 day supply per fill
  - 30 mg tablets: 1 tablet per day, 14 day supply per fill

**AUTHORIZATION DURATION:** One 14 day course of therapy. Additional courses of Zurzuvae for future cases of PPD associated with additional pregnancies will be reviewed for medical necessity based on the above criteria. More than one administration of Zurzuvae per pregnancy/birth is considered investigational and not covered.

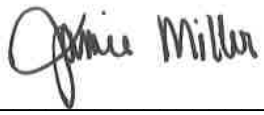
If an exception is made, Zurzuvae will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: March 1, 2024

Devised: 2/12/24
Reviewed: 3/1/24 – annual review

| Geisinger | **POLICY NUMBER: 796.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Airsupra** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Airsupra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Airsupra may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation for as needed use to treat or prevent asthma attacks **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to one beta-2 agonist (albuterol or levalbuterol) **AND** budesonide-formoterol (generic Symbicort)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 32.1 grams per 30 days

If an exception is made, Airsupra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

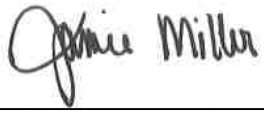
**FORMULARY ALTERNATIVES:**

albuterol HFA, levalbuterol HFA, budesonide/formoterol (generic Symbicort)

| Geisinger | POLICY NUMBER: 796.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Airsupra |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

Geisinger

**POLICY NUMBER: 797.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Augtyro**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Augtyro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Augtyro may be made for members who meet the following criteria:

- Medical record documentation that Augtyro is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS1*-positive

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 capsules per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Augtyro is configured as a prior authorization for new starts only. Augtyro will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Augtyro will be paid for under the member's prescription drug benefit.

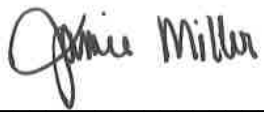
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

| Geisinger | POLICY NUMBER: 798.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Ogsiveo** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ogsiveo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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4. ***NCQA*** – National Committee for Quality Assurance.
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A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Ogsiveo may be made for members who meet the following criteria:

- Medical record documentation that Ogsiveo is prescribed by a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of desmoid tumor(s) / aggressive fibromatosis (AF) with documentation of progression **AND**
- Medical record documentation the desmoid tumor(s) are not amenable to surgery **AND** require systemic treatment

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Ogsiveo is configured as a prior authorization for new starts only. Ogsiveo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Ogsiveo will be paid for under the member's prescription drug benefit.

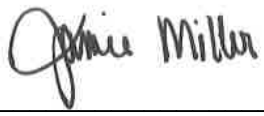
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

| Geisinger | **POLICY NUMBER: 799.0** |
|---|---|
| **POLICY AND PROCEDURE**<br>**PHARMACY**<br>MANUAL | **SECTION: Commercial Drug**<br>**SUBJECT: Breyna** |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Breyna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Breyna may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of asthma **OR** chronic obstructive pulmonary disease (COPD) b
- Medical record documentation of therapeutic failure on generic budesonide/formoterol **AND** generic fluticasone/salmeterol diskus

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10.3 grams per 30 days

If an exception is made, Breyna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

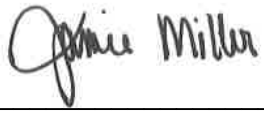
**FORMULARY ALTERNATIVES:**

budesonide/formoterol, fluticasone/salmeterol diskus, Wixela, fluticasone/salmeterol HFA, Advair HFA, Breo Ellipta, Dulera

| Geisinger | POLICY NUMBER: 799.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Breyna |

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

| Geisinger | POLICY NUMBER: 800.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Iwilfin |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Iwilfin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Iwilfin may be made for members who meet the following criteria:

- Medical record documentation that Iwilfin is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation that Iwilfin is being used to reduce the risk of relapse in patients with high-risk neuroblastoma (HRNB) **AND**
- Medical record documentation that the patient demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 tablets per day, 30 day supply per fill

**RE-AUTHORIZATION CRITERIA:** Iwilfin is configured as a prior authorization for new starts only. Iwilfin will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

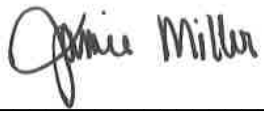
If an exception is made, Iwilfin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

| Geisinger | POLICY NUMBER: 801.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Jesduvroq |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jesduvroq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Jesdurvroq may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of anemia due to chronic kidney disease **AND**
- Medical record documentation that member has been receiving dialysis for at least four months **AND**
- Medical record documentation of a Hemoglobin less than or equal to 11 g/dL **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron

**NOTES:**

- For continuation of therapy, a repeat Hgb should be submitted after 12 months of therapy.
- In individuals whose Hgb is greater than or equal to 12g/dL or rises by 1g/dL in any two-week period, additional doses should be withheld.
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 1 mg, 2 mg, 4 mg tablets: 1 tablet per day
  - 6 mg tablets: 2 tablets per day
  - 8 mg tablets: 3 tablets per day

**AUTHORIZATION DURATION:** Approval of Jesduvroq will be given for an initial duration of 12 months. Subsequent authorization will be considered based on the policy criteria.

If an exception is made, Jesduvroq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jessie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 801.0**

**SECTION: Commercial Drug**
**SUBJECT: Lodoco**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lodoco for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Lodoco may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lodoco is prescribed to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death **AND**
    - Medical record documentation of established atherosclerotic cardiovascular (ASCVD) disease [Clinical ASCVD includes acute coronary syndromes, history of myocardial infarction (MI), angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral arterial disease (PAD)] **OR**
    - Medical record documentation of 2 or more risk factors for cardiovascular disease (e.g., family history of premature atherosclerotic cardiovascular disease (ASCVD), primary hypercholesteremia, metabolic syndrome, chronic kidney disease (CKD), current smoker, congestive heart failure, coronary artery calcium (CAC) score greater than 400, etc.) **AND**
- Medical record documentation that member is currently receiving standard of care therapy for chronic coronary disease (e.g., antiplatelets, anticoagulants, lipid-lowering agents, beta-blockers, renin-angiotensin inhibitors) unless contraindicated or not tolerated **AND**
- Medical record documentation of creatinine clearance greater than or equal to 15 mL/min/1.73m$^2$

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Lodoco will be paid for under the member's prescription drug benefit.

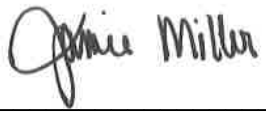
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

| Geisinger | POLICY NUMBER: 803.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Motpoly XR |

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Motpoly XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Motpoly XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of weight greater than or equal to 50 kilograms (kg) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be oral lacosamide immediate-release

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 100 mg capsule: 1 capsule per day
  - 150 mg & 200 mg capsules: 2 capsules per day

If an exception is made, Motpoly XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 803.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Motpoly XR |

**FORMULARY ALTERNATIVES:**

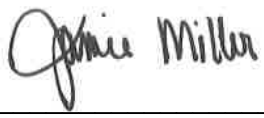
For patients aged ≥ 1 month of age: lacosamide IR*, carbamazepine, levetiracetam IR, phenobarbital, phenytoin, pregabalin

Additional formulary alternatives for patients over certain ages: lamotrigine IR (2+), topiramate IR (2+), topiramate ER (2+), gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

Geisinger

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**POLICY NUMBER: 804.0**

**SECTION: Commercial Drug**
**SUBJECT: Velsipity**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Velsipity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical

An exception for coverage of Velsipity may be made for members who meet the following criteria:

- Medical record documentation that Velsipity is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary biologics for the treatment of ulcerative colitis that are self-administered **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Entyvio **AND** infliximab **AND**
- Medical record documentation that Velsipity is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ulcerative colitis at six (6) months of Velsipity therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Velsipity therapy.

If an exception is made, Velsipity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

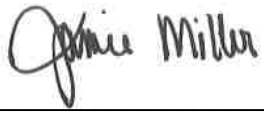
**FORMULARY ALTERNATIVES:**

Humira*, adalimumab-FKJP*, Hadlima*, Yusimry*, Rinvoq*, Xeljanz/XR*, Simponi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24

Geisinger

**POLICY NUMBER: 805.0**

**POLICY AND PROCEDURE**
**PHARMACY**
MANUAL

**SECTION: Commercial Drug**
**SUBJECT: Xphozah**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | |
| Medicare | | ACA | X |
| GHP Kids | X | Self-Insured | X |

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xphozah for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

**REQUIRED DEFINITIONS:**

1. ***Attachment*** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. ***Exhibit*** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. ***Devised*** – the date the policy was implemented.
4. ***Revised*** – the date of every revision to the policy, including typographical and grammatical changes.
5. ***Reviewed*** – the date documenting the annual review if the policy has no revisions necessary.

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:

A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**PROCEDURE:**

An exception for coverage of Xphozah may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Xphozah is prescribed by a nephrologist **AND**
- Medical record documentation of a diagnosis of chronic kidney disease (CKD) on dialysis **AND**
- Medical record documentation that Xphozah is being used as add-on therapy to control serum phosphorus levels **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcium acetate **AND** sevelamer carbonate **AND** lanthanum carbonate

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

If an exception is made, Xphozah will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

| Geisinger | POLICY NUMBER: 805.0 |
|---|---|
| POLICY AND PROCEDURE<br>**PHARMACY**<br>MANUAL | SECTION: Commercial Drug<br>SUBJECT: Xphozah |

**FORMULARY ALTERNATIVES:**

Auryxia*, calcium acetate, Fosrenol, lanthanum carbonate, sevelamer carbonate, Velphoro*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: Jamie Miller

Title: Associate Vice President, Managed Care Pharmacy Services

Date: April 10, 2024

Devised: 4/10/24