"What's New" Medical Policy Updates May 2024

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of April that will become **effective June 15, 2024** (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within members written benefit documents. Coverage may vary by line of business and providers and members are encouraged to verify benefit questions regarding eligibility before applying the terms of the policy.

MP046 Progressive Stretch Devices – Revised – Revised Language

INDICATIONS: Requests for coverage require pre-certification through the Medical Management Department and must include active range of motion/ passive range of motion measurements and functional limitations. Equipment must be obtained through contracted Durable Medical Equipment vendor(s)

Dynamic low-load progressive stretch devices for the knee, elbow, wrist, or finger may be considered **medically necessary as an adjunct to physical therapy** when there is documentation of unfavorable response to conventional methods such as prior surgery or physical/occupational therapy for restoring joint motion and EITHER of the following criteria is met:

- Persistent joint stiffness with documented loss of function or spasticity caused by immobilization in a sub-acute injury or post-medical intervention period (i.e., at least 3 weeks and no more than 4 months after injury or operation) which interferes with activities of daily living; **OR**
- In acute post-medical intervention period with prior documented history of motion stiffness/loss and member has undergone recent additional surgery or medical intervention to improve the range of motion of the previously affected joint.

LIMITATIONS:

Continued authorization will be contingent upon documented clinical improvement including a clinical assessment by a physician and/or an allied health professional after onset of therapy. This assessment should include active or passive range of motion, functional progress and compliance with wear time.

For Medicaid lines of Business:

Joint Active Systems (JAS) are considered medically necessary when recommended by a physician for the treatment of joint stiffness in the hand, elbow, wrist, knee, ankle and forearm. The individual must be able to control the device and follow time-limited exercises.

JAS is not a substitute for hands-on physical therapy. Pediatric patients must have adult supervision.

EXCLUSIONS:

- Use of dynamic splinting in the management of joint injuries of the shoulder, ankle, toe or other joints not listed under Indications is considered experimental, investigational and unproven and not medically necessary and therefore is NOT COVERED.
- Use when conventional methods of treating a stiff or contracted joint have not been utilized or when physical therapy is not involved for assessment of progress is **NOT COVERED**
- Use with an unhealed fracture of affected joint is NOT COVERED
- The prophylactic use of dynamic splinting in the management of chronic contractures (no significant change in motion for 4 months and no new surgery to improve the joint) and chronic joint stiffness due to trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, multiple sclerosis, muscular dystrophy, plantar fasciitis or cerebral palsy is considered experimental, investigational and unproven and not medically necessary and therefore is NOT COVERED.
- Continued use of a progressive stretch device in the management of chronic conditions (i.e., no significant change in motion for a 4-month period) and joint stiffness to maintain a current level of

function once therapeutic goals of treatment have been achieved and no additional functional progress is apparent or expected to occur is **NOT COVERED**

- Passive jaw rehabilitation devices such as, but not limited to the TheraBite® system for the treatment of jaw hypomobility are considered investigational and are **NOT COVERED**. There is insufficient evidence to conclude that this device is effective for mandibular hypomobility.
- There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of patient-actuated serial stretch (PASS) devices for any indication. The use of these devices including, but not limited to ERMI pneumatic extensionaters, or hydraulic flexionaters, either alone or as an adjunct to a PT program is considered experimental, investigational and unproven and not medically necessary and therefore is NOT COVERED.

MP076 HH/DME Hyperbilirubinemia – Revised – Updated Criteria

INDICATIONS: Home phototherapy treatment for the diagnosis of <u>physiologic jaundice of the term</u> <u>newborn is considered appropriate when the following criteria are met.</u>

- The infant is eligible for hospital discharge; and
- There are no known hyperbilirubinemia neurotoxicity risk factors; and
- Total serum bilirubin concentration is no more than 1 mg/dL above the phototherapy treatment threshold; and
- The infant is otherwise healthy, active and feeding well; and
- Caregivers are capable of understanding and following direction
- Total bilirubin level must be greater than 12 mg/dL and less than 22 mg/dL*; and
- The infant is otherwise healthy, active and feeding well
- Caregivers are capable of understanding and following direction

<u>NOTE:</u> Requests for home phototherapy for diagnoses other than physiologic jaundice of the term newborn, or when bilirubin levels are outside of the indicated levels, should be reviewed with a Plan medical director



- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin.
 Risk factors = isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis, or albumin < 3.0g/dL (if measured)
- For well infants 35-37 6/7 wk can adjust TSB levels for intervention around the medium risk line. It is an option to intervene at lower TSB levels for infants closer to 35 wks and at higher TSB levels for those closer to 37 6/7 wk.
- It is an option to provide conventional phototherapy in hospital or at home at TSB levels 2-3 mg/dL (35-50mmol/L) below those shown but home phototherapy should not be used in any infant with risk factors.





Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation Pediatrics (2022) 150 (3): e2022058859.

Age (hours) Phototherapy	Consider phototherapy	Phototherapy	Stop
<u>25-48</u>	≥ 12 mg/dL	<u>≥ 15 mg/dL</u>	<u>≤ 8 mg/dL</u>
- 49-72 →72	≥ 13 mg/dL ≥ 17 mg/dL	≥ 10 mg/dL ≥ 20 mg/dL	<u>≤ 14 mg/dL</u>

(*-based on American Academy of Pediatrics Recommendations and practice patterns and recommendation of Geisinger Health System physicians)

MP097 Genetic Testing for BRCA – Revised – Revised Indications

DESCRIPTION:

Approximately 7-10% of all breast cancers, 20-25% of all ovarian cancers, 10-17% of prostate cancers, and 5-10% of pancreas cancers can be attributed to a dominantly inherited susceptibility.

Multi-gene panel testing is the most cost-effective and accurate approach to characterize familial cancer risk. BRCA1 and BRCA2 testing alone is no longer the clinical standard of care. Mutations in BRCA1 and BRCA2 have been identified in up to 50% of the inherited forms of hereditary breast and ovarian cancers, however, additional high-and moderate-risk genes have been discovered that may (1) explain familial cancer risk, (2) provide future cancer risk information, or (3) direct targeted therapeutic options.

Disease-specific panels may change from year to year based on available evidence and technological advancements. Germline multigene panel testing (MGPT) for moderate and high-penetrance cancer susceptibility genes should ultimately include ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, TP53) and full duplication and deletion analysis (i.e., detection of large genomic rearrangements).

Up to 12% of genomic tumor profiling or sequencing tests will reveal a germline pathogenic variant. some germline variants are highly predictive of response to specific cancer-directed therapies, such as poly-ADP ribose polymerase (PARP) inhibitors in patients with breast or ovarian cancer who have germline BRCA1/2 variants. Some reports suggest up to 50- 60% likelihood that when a BRCA sequencing variant is reported in any tumor type, it will be present in the germline.

Panel testing is considered medically necessary once per lifetime for persons who meet one or more National Comprehensive Cancer Network (NCCN) testing criteria for high-penetrance breast, ovarian, or pancreatic cancer susceptibility gene

INDICATIONS:

The Plan considers molecular susceptibility testing for hereditary breast and ovarian cancer (HBOC) via panel testing, medically necessary in **ANY** of the following indications:

NOTE: STAT testing of BRCA1, BRCA2, and PALB2 may be required in specific clinical scenarios for surgical or therapeutic decision making. Panel testing is considered medically necessary and will be approved for members undergoing this sequential testing.

Members with a personal history of an HBOC-related cancer, at any age, regardless of family history:

- Breast cancer (includes histologic subtypes: invasive lobular, invasive ductal, inflammatory, papillary, and DCIS. (LCIS excluded.)
- Ovarian, fallopian tube, primary peritoneal cancer
- Pancreatic adenocarcinoma
- Prostate adenocarcinoma

STAT testing of BRCA1, BRCA2, and PALB2 may be required in specific clinical scenarios for surgical or therapeutic decision making. Panel testing is considered medically necessary and will be approved for members undergoing this sequential testing.

Members with any other type of malignancy where somatic (tumor-based) testing demonstrates a BRCA1 or BRCA2 variant within the tumor sample. <u>Members without a personal history of breast cancer, ovarian cancer/fallopian</u> tube/primary peritoneal cancer, or pancreatic adenocarcinoma, but with a known mutation in a cancer susceptibility gene in the member, or within the family

Confirmatory testing and counseling for known variants (including 185delAG, 5382insC, or 6174delT).

<u>Members without a personal history of cancer, but with a family history of meeting ANY</u> <u>ONE of the following criteria:</u>

1. A blood relative with a mutation in a known cancer susceptibility gene, OR.

2. A blood relative with a mutation in a hereditary cancer syndrome gene found on tumor testing who is unable to undergo germline testing, OR

At least one first or second-degree blood relative with a history of breast cancer diagnosed at 50 years or younger

3. At least one first or second-degree blood relative diagnosed with triple negative breast cancer OR bilateral breast cancer OR two separate breast primaries, at any age

4. At least one first or second-degree blood relative with any of the following cancers, diagnosed at any age:

- a. male breast cancer
- b. epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer
- c. pancreatic adenocarcinoma
- d. prostate cancer (metastasis or high-grade diagnosis not required)
- e. two close relatives with any combination of breast, ovary, pancreas, or prostate cancers

5. At least 5% mutation probability using a validated risk tool (eg. Tyrer-Cuzick v8, BRCAPro, or CanRisk).

6. A reported history of Ashkenazi Jewish ancestry with at least one first or second-degree relative with an HBOC cancer (eg. breast, ovarian, pancreas, or prostate cancer) at any age.

7. The member has a personal or family history suggestive of a rare hereditary cancer syndrome that does not fall into the above criteria. Examples: Li-Fraumeni syndrome (TP53), Peutz-Jeghers syndrome (STK11), or PTEN Hamartoma Tumor syndrome (aka Cowden syndrome, PTEN).

a. Combination of any two of the following in a patient or close relative: macrocephaly, cerebellar tumors or adult Lhermitte-Duclose disease, autism spectrum disorder, intellectual disability, macular degeneration of the glans penis, one ganglioneuroma or at least two hamartomas of the GI tract, follicular thyroid cancer, breast cancer, endometrial cancer, or two or more trichilemmomas, oral papillomatosis, verrucous facial papules, or palmoplantar keratoses.

b. Close relative with acute lymphoblastic leukemia (ALL), soft tissue or bone sarcoma, brain cancer, chorioid plexus carcinoma, rhabdomyosarcoma, or adrenocortical carcinoma.

7. A likely pathogenic or pathogenic variant in an above listed gene (see description) identified on tumor testing.

MP223 Discography – Revised – Revised Language

INDICATIONS:

Lumbar provocative discography is considered medically necessary for evaluation for disc pathology in members with persistent, severe low back pain and abnormal vertebral interspaces on magnetic resonance imaging, when surgical intervention is being considered.

EXCLUSIONS: The Plan does **NOT** provide coverage for the use of functional anesthetic discography (FAD) because it is considered experimental, investigational or unproven and therefore not medically necessary. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

The Plan does **NOT** provide coverage for the use of cervical and thoracic provocative discography because it is considered experimental, investigational or unproven and therefore not medically necessary. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

MP233 Autologous Injectable Platelet and Blood Products – Revised – Revised Language

EXCLUSIONS: Unless otherwise noted:

The Plan does **NOT** provide coverage for Autologous Platelet-Derived Growth Factor for any indication including but not limited to surgical wounds, chronic non-healing wounds, Epicondylitis, Plantar Fasciitis, Dupuytren's Contracture, bone healing and fusion, tendinopathy and sinus surgery because it is considered **experimental, investigational or unproven** and therefore not medically necessary. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for bone marrow plasma or bone marrow-derived mesenchymal stem cell injection for any orthopedic condition because it is considered experimental, investigational or unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for autologous platelet gel following total knee arthroplasty or for treatment of diabetic foot ulcer because it is considered experimental, investigational or unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for platelet-rich fibrin for intra-bony defects in chronic periodontitis and rotator cuff tears because it is considered experimental, investigational or unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for adipose-tissue-derived stem cells injection (Habeo cell therapy) for the treatment of scleroderma (systemic sclerosis) or any other indications because it is considered experimental, investigational or unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The following policies have been reviewed with no change to the policy section. Additional references or background information was added to support the current policy.

MP033 Varicose Vein Treatments MP037 Home Phlebotomy Program MP039 Home Uterine Monitoring MP044 Aquatic Therapy MP062 TMLR MP081 Chelation Therapy MP127 Prolotherapy

MP165 Treatment of Vestibular Disorders

MP170 Gene Expression Profiling for Breast Cancer Treatment

MP179 Photodynamic Therapy for Oncology Applications

MP198 Pulse Oximetry for Pediatric Home Use

MP212 Non-Contact low-frequency Ultrasound Management (MIST Therapy)

MP277 Vision Therapy/ Orthoptics

MP293 Intrathecal Infusion Pump

MP299 Measurement of Serum Antibodies to Infliximab and Adalimumab

MP335 Extracorporeal Photopheresis

MP351 Myoelectric Upper Extremity Orthotics