"What's New" Medical Policy Updates May 2021

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**, **2021** (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within the insured individuals 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.

MP170 Gene Expression Profiling for Breast Cancer Treatment – (Revised) – Added BCI Coverage

Breast Cancer Index™ (BCI)

The Plan considers Breast Cancer Index (BCI) as medically necessary for prediction of benefit from extended endocrine therapy when considering adjuvant systemic therapy for postmenopausal women with invasive breast cancer when **ALL** of the following criteria are met:

- Pathology reveals invasive carcinoma of the breast that is ER+ and/or PR+ and HER2-; and
- Member has early-stage disease (T1-3, pN0, M0); and
- member is lymph node negative; and
- member has no evidence of distant breast cancer metastasis (i.e., non-relapsed); and
- Test results will be used in determining treatment management of the member for chemotherapy and/or extension of endocrine therapy.

LIMITATIONS:

The test(s) are is-covered once per primary tumor, per individual.

EXCLUSIONS:

Unless coverage is mandated, the Plan does NOT provide coverage for any other assays of genetic expression in breast tumor tissue (e.g. BluePrint [™], TargetPrint®, Mammostrat® Breast Cancer Test, the Breast Cancer Index SM, BreastOncPx[™], NexCourse® Breast IHC4, PreciseDx[™] Breast Cancer Test, BreastPRS[™], and the Rotterdam Signature 76-Panel) because they are considered experimental, investigational or unproven.

MP179 Photodynamic Therapy for Oncology Applications – (Revised) – Added Exclusion

EXCLUSIONS: The Plan does **NOT** provide coverage for photodynamic therapy (PDT) with light-activated porfimer sodium (Photofrin®) as a treatment for other head and neck malignancies because it is considered **experimental**, **investigational or unproven**. 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 test on health outcomes when compared to established tests or technologies.

The Plan does NOT provide coverage for photodynamic therapy (PDT) as a treatment for malignancies not listed under Indications because it is considered experimental, investigational or unproven. 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 test on health outcomes when compared to established tests or technologies. Please see: MP259 Phototherapy for the Treatment of Dermatological Conditions

MP217 Polysomnography and Sleep Studies – (Revised) – Added Indications INDICATIONS:

I. Polysomnography testing may be an eligible benefit when provided in a facility based sleep study laboratory which meets **ALL** of the following criteria:

- a. The center is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder laboratories may be covered even in the absence of direct supervision by a physician when data is interpreted by a board certified sleep specialist or physician who fulfills eligibility criteria for the sleep medicine certification exam; and
- b. The member is referred to the sleep center by a physician after a comprehensive sleep evaluation is completed, and the center maintains a record of the physician's orders and comprehensive sleep evaluation; **and**
- c. The need for diagnostic testing is confirmed by medical evidence e.g. medical histories, examinations and laboratory tests; **and**
- d. Scheduling of a follow-up visit with a physician to review results is standard.
- II. The Plan considers facility-based polysomnography medically necessary for ANY of the following:
 - a. The diagnosis of sleep related breathing disorders
 - b. To monitor the response to treatment or adjust treatment
 - c. In combination with multiple sleep latency testing in the evaluation of suspected narcolepsy
 - d. In the evaluation of sleep related behaviors that are violent or potentially injurious to the member patient or others
 - e. In certain atypical or unusual parasomnias

The Plan considers facility-based polysomnography medically necessary in ANY of the following:

- a. in members patients with neuromuscular disorders and sleep related symptoms
- b. portable or unattended sleep studies are technically inadequate to make a diagnosis of obstructive sleep apnea
- to assist in the diagnosis of paroxysmal arousals or other sleep disruptions thought to be seizure related
- d. in a presumed parasomnia or sleep related seizure disorder that does not respond to conventional therapy
- j. when there is a strong indication of periodic limb disorder

MP233 Autologous Injectable Platelet and Blood Products – (Revised) – Added Exclusions

EXCLUSIONS:

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**. 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. 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. 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. 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. 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.

MP324 Genetic Testing for Non-Cancer Heritable Disease Carrier Status – (Revised) – Added Criteria for Coverage

Fragile X syndrome

Genetic testing may be considered medically necessary when one or more of the following criteria are met:

- Members of either sex with intellectual disability, developmental delay or autism spectrum disorder
- Members seeking reproductive counseling who have a family history of fragile X syndrome or a family history of undiagnosed intellectual disability
- Prenatal testing of fetuses in pregnant members who are known carriers
- Affected members who have had a positive cytogenetic fragile X test result who are seeking further counseling related to the risk of carrier status
- Members with unexplained ovarian insufficiency or failure or an elevated follicle-stimulating hormone level before the age of 40

Peutz-Jeghers Syndrome:

Genetic testing may be considered medically necessary when:

There is a known family history of STK11 (LKB1) gene mutation; or

The member has a clinical diagnosis of PJS based on at least TWO of the following features:

- At least TWO PJS-type hamartomatous polyps of the gastrointestinal tract; or
- Mucocutaneous hyperpigmentation of the mouth, lips, nose, eyes, genitalia, or fingers; or
- A family history of PJS.

Noonan Syndrome:

Genetic testing may be considered medically necessary when:

There is a known family history of TPN11, SOS1, RADF1 and KRAS gene mutation; or

The member is suspected of Noonan syndrome due to a combination of any of the following:

- A characteristic facial appearance.
- Short stature.
- Heart defect present at birth (congenital heart defect).
- A broad or webbed neck.
- Minor eye problems such as strabismus in up to 95 percent of individuals.
- Bleeding problems such as a history of abnormal bleeding or bruising.
- An unusual chest shape with widely-spaced and low set nipples.
- Developmental delay of varying degrees, but usually mild.
- Undescended testes

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

MP046 Progressive Stretch Devices

MP062 TMLR

MP076 HH/DME Hyperbilirubinemia

MP081 Chelation Therapy

MP083 Contact Lenses

MP097 Genetic Testing for BRCA

MP127 Prolotherapy

MP165 Treatment of Vestibular Disorders

MP198 Pulse Oximetry for Pediatric Home Use

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

MP223 Discography

MP277 Vision Therapy/ Orthoptics

MP293 Intrathecal Infusion Pump

MP335 Extracorporeal Photopheresis