"What's New" Medical Policy Updates May 2020

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the months of April that will become **effective June 15, 2020** (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.

MP033 Varicose Vein Treatments - (Revised) - Added Program Exception Note

**NOTE: For Medicaid Business Segment - cyanoacrylate-based therapy (cpt codes 36482, 36483) requires a Program Exception

MP083 Contact Lenses – (Revised) – Added Coverage

INDICATIONS:

For Commercial Business Segment:

Therapeutic soft (hydrophilic) contact lenses may be considered medically necessary when used as moist corneal bandages for the treatment of acute corneal abrasion, corneal ulcers and erosion, poorly healing eye wounds, or for other therapeutic reasons as determined by a Plan medical director.

Contact lenses, including gas-permeable rigid contact lenses (known as RGP or GP lenses), are covered for the treatment of progressive eye diseases, including but not limited to keratoconus.

MP097 Genetic Testing for BRCA – (Revised) – Revised Title; Added Criteria

Blood Relatives: NCCN defines blood relative as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on same side of family

Members with a personal history of prostate cancer (Gleason score >7) at any age with:

- One or more close first- or second-degree blood relatives with breast cancer and/or epithelial ovarian cancer/fallopian tube/primary peritoneal cancer, or pancreatic or prostate cancer (Gleason score >7) at any age; or
- 2. One or more-close first- or second-degree blood relative who has a BRCA1 or BRCA2 mutation.

Therapeutic companion testing:

BRCA testing using an FDA-approved companion diagnostic is considered medically necessary when the following criteria are met:

- The member has a diagnosis of cancer; and
- The specific therapeutic is FDA- approved and treatment eligibility is dependent upon BRCA1/2 testing (e.g.,

Members with ovarian cancer who are considering treatment with Lynparza or Rubraca; members with metastatic breast cancer who are considering treatment with Lynparza)

PALB2 mutation testing:

The Plan considers full sequence analysis molecular testing for PALB2 mutation to be medically necessary when **ALL** of the following are met:

- The member is 18 years of age or older
- Member has met criteria for BRCA1/2 analysis:
- Member tested negative for BRCA1/2

The Plan considers known familial mutation analysis for PALB2 mutation to be medically necessary when ALL of the following are met:

- The member is 18 years of age or older
- A mutation in PALB2 has been identified in 1st, 2nd, or 3rd degree relative(s)

MP133 Meniscal Allograft - (Revised) - Clarified Language

INDICATIONS:

Meniscal allograft transplantation when obtained from a suitable cadaver is considered to be medically necessary to restore knee function when the following criteria are met:

- Patients Members with damaged or absent menisci with more than half of the meniscus missing.
- Patients Members should be skeletally matured with documentation of closure of the growth
 plates but also considered too young for other reconstructive knee surgery such as total knee
 arthroplasty.
- Persistent activity-related pain that is refractory to conservative therapy
- Minimal to no arthritis
- Patient Member is not considered to be obese (BMI of 40kg/m² or greater)

MP165 Treatment of Vestibular Disorders - (Revised) - Added Language

INDICATIONS:

Particle repositioning maneuvers (i.e. Epley Canalith maneuver and/or Semont Maneuver) may be considered medically necessary for the treatment of benign paroxysmal positional vertigo and benign positional vertigo other than paroxysmal when evidenced by a Dix-Hallpike test and/or clinical signs and symptoms indicative of BPPV are present.

Vestibular function testing by electronystagmography (ENG) and videonystagmography testing batteries, caloric testing, or rotational chair testing may be considered medically necessary when the following conditions have been met:

- The member is experiencing symptoms of a vestibular disorder (eg, dizziness, vertigo, imbalance);
- A clinical evaluation, including the Dix-Hallpike test if indicated, has not identified the cause of the symptoms.

MP179 Photodynamic Therapy for Oncology Applications – (Revised) – Revised Title; Added Criteria

INDICATIONS:

The Plan considers photodynamic therapy (PDT) with light-activated porfimer sodium (Photofrin®) medically necessary for the treatment of EITHER of the following specific types of cancer meeting the listed criteria:

- Esophageal cancer for EITHER of the following:
 - Completely or partially obstructing esophageal cancer that cannot be treated satisfactorily with neodymium:yttrium-aluminum-garnet (Nd:YAG) laser therapy
 - Barrett's esophagus carcinoma in situ and high-grade disease in individuals who are not esophagectomy candidates (e.g., obstructive disease with limited pulmonary function and/or cardiovascular disease with poor cardiac function that precludes surgical resection)
- Lung cancer for EITHER of the following:
 - Early-stage non-small cell lung or endobronchial cancer (NSCLC) in individuals who are not candidates for surgery or radiotherapy (e.g., obstructive disease with limited pulmonary function and/or cardiovascular disease with poor cardiac function that precludes surgical resection)
 - Advanced-stage obstructing endobronchial non-small cell lung cancer (NSCLC), for the reduction of obstruction and palliation of symptoms
- Unresectable cholangiocarcinoma used in combination with stenting

MP223 Discography - (Revised) - Revised Title; Added Content

DESCRIPTION:

Discography or provocative discography is an invasive diagnostic procedure that uses x-rays to examine the intervertebral discs of the spine. A dye is injected into the injured disc or series of discs. The dye makes the disc visible on a fluoroscope monitor and x-ray film. Discograms are used to locate precisely which discs are damaged and are causing back pain.

Functional anesthetic discography (FAD) is a diagnostic procedure that involves injecting an anesthetic agent directly into a spinal disc. During this procedure, under light sedation and x-ray guidance, a small catheter is inserted into the suspected disc and anchored in place with a small balloon. After recovering from light sedation, the patient is asked to engage in physical activity to reproduce pain. Local anesthetic is then injected in the disc believed to be causing the patient's pain. Reduction in pain is considered diagnostic. If the injection into a specific disc relieves the patient's back pain, the disc can be further evaluated for potential treatment. If the test does not relieve the patient's pain, the physician can investigate other possible causes of pain.

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**. 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**. 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.

MP265 Proteomic Serum Analysis – (Revised) – Added Language/Criteria

Xpresys Lung and BDX-XL2 (Xpresys Lung 2) are plasma-based proteomic screening tests that measures the relative amount of proteins associated with lung cancer using multiple reaction monitoring mass spectroscopy. The testing is proposed to aid in differentiating likely benign from likely malignant nodules.

REVEAL Lung Nodule Characterization is a plasma protein biomarker test proposed to aid in characterizing indeterminate pulmonary nodules (4-30 mm) in current smokers aged 25 years and older. Using immunoassay, microarray, and magnetic nanoparticle detection techniques, the REVEAL Lung Nodule Characterization score is presented on a scale from 0 to 100 with a single cut point at 50. The score is based on an algorithm using factors from the patient's history (smoking history, age, and nodule size), and the presence of three blood proteins associated with lung cancer (epidermal growth factor receptor [EGFR], prosurfactant protein B (ProSB), and tissue inhibitor of metalloproteinases 1 (TIMP1).

Medicare Business Segment:

In compliance with Novitas LCD L35396 the OVA1 proteomic assay will be covered according to the FDA label. OVA1 is intended only for members, 18 years and older, who are already selected for surgery because of their pelvic mass. It is not intended for ovarian cancer screening or for a definitive diagnosis of ovarian cancer.

In compliance with Novitas LCD L35396 the Risk of Ovarian Malignancy Algorithm (ROMA™) serum test will be covered to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy at surgery. ROMA™ will be considered reasonable and necessary for women who meet the following FDA labeling criteria:

- Over age 18;
- Ovarian adnexal mass present for which surgery is planned; and,
- Not yet referred to an oncologist.

In compliance with Novitas LCD L35396 the Veristrat proteomic assay will be covered to predict the benefit of single-agent chemotherapy or EGFR Tyrosine Kinase Inhibitor treatment in patients with non-small cell lung cancer with an unknown or wild-type variant of EGFR, or to identify patients with particularly aggressive disease.

MoIDx has determined that BDX-XL2 test will be covered for the management of a lung nodule, between 8 and 30mm in diameter, in patients 40 years or older and with a pre-test cancer risk (as assessed by the Mayo Clinic Model for Solitary Pulmonary Nodules) of 50% or less.

EXCLUSIONS:

Unless otherwise mandated, the Plan does **NOT** provide coverage for Proteomic Serum analysis to Identify Ovarian Cancer 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 test on health outcomes when compared to established tests or technologies.

Any use of VeriStrat® serum proteomic testing except as noted above is considered experimental/investigational or unproven and **NOT COVERED**.

Unless otherwise mandated, the Plan does **NOT** provide coverage for Proteomic Serum analysis to Identify Lung Cancer

(Xpresys Lung, BDX-XL2, REVEAL Lung Nodule Characterization) 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 test on health outcomes when compared to established tests or technologies.

The Plan does **NOT** provide coverage for Proteomic Serum analysis to bladder cancer (Cxbladder[™] Detect, Cxbladder[™] Monitor) 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 test on health outcomes when compared to established tests or technologies.

MP277 Vision Therapy/Orthoptics – (Revised) – Added Medicare Language

Medicare Business Segment:

Medicare does not have a National Coverage Determination (NCD) or a Local Coverage Determination (LCD) for vision therapy/orthoptics used for treating amblyopia.

Medicare does not have an NCD or an LCD for vision therapy/orthoptics used to treat convergence insufficiency.

Medicare does not have an NCD or an LCD for Vision Restoration Therapy (VRT) used for treating visual field deficits following stroke or neurotrauma.

Medicare covers rehabilitation services for members with a primary vision impairment diagnosis when provided by a qualified occupational or physical therapist (or a person supervised by a qualified therapist) and when provided according to a written treatment plan written by a physician.

MP335 Extracorporeal Photopheresis – (NEW)

DESCRIPTION: Extracorporeal photopheresis (ECP) is a leukapheresis-based immunomodulatory procedure that involves three steps. First, the patient's blood is centrifuged to separate the leukocyte-rich portion from the rest of the blood; then the photosensitizer agent 8-methoxypsoralen is added to the lymphocyte fraction, which is then exposed to ultraviolet-A light at a dose of 1 to 2 J/cm2. Lastly, the light-sensitized lymphocytes are reinfused into the patient.

INDICATIONS: Extracorporeal photopheresis may be considered medically necessary for any one of the following indications:

- Palliative treatment of skin manifestations of cutaneous T-cell lymphoma (e.g., mycosis fungoides, Sézary syndrome) that are refractory to other therapy
- Acute or chronic graft versus host disease refractory to standard immunosuppressive drug treatment
- Acute cardiac allograft rejection refractory to standard immunosuppressive drug treatment
- Bone marrow transplant rejection or failure
- Stem cell transplant complications
- Bronchiolitis obliterans syndrome following lung allograft transplantation

FOR MEDICARE BUSINESS SEGMENT:

Per National Coverage Determination (NCD) for Extracorporeal Photopheresis (110.4), extracorporeal photopheresis may be considered medically necessary for any one of the following indications:

- Palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other therapy
- Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment

- Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment
- Extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS)
 following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets the conditions outlined in NCD 110.4

EXCLUSIONS: The Plan does **NOT** provide coverage for the use of Extracorporeal photopheresis for any indication not listed in this policy because those applications are 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 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.

MP037 Home Phlebotomy Program

MP039 Home Uterine Monitoring

MP044 Aquatic Therapy

MP046 Progressive Stretch Devices

MP062 TMLR

MP076 HH/DME Hyperbilirubinemia

MP081 Chelation Therapy

MP127 Prolotherapy

MP198 Pulse Oximetry for Pediatric Home Use

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

MP217 Polysomnography and Sleep Studies

MP233 Autologous Injectable Platelet and Blood Products

MP293 Intrathecal Infusion Pump