"What's New" Medical Policy Updates June 2017

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of May that will become **effective July 15, 2017** (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.

MP004 Biofeedback - REVISED – (Revised Exclusions)

EXCLUSIONS:
For contracts in which biofeedback is not specifically excluded, biofeedback is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.

~~Per CMS~~, Home use (unsupervised) of biofeedback therapy is not covered (e.g., RESPeRATE® , Innosense®).
Coverage for biofeedback for any indication other than as outlined in this policy is considered to be Experimental, Investigational or Unproven and therefore **NOT COVERED.** Specific benefit exclusions may also apply per the **Exclusions** section of the applicable benefit documents.

MP054 Prophylactic Mastectomy - REVISED – (Revised Indications)

INDICATIONS:
Prophylactic mastectomy *may* be considered medically necessary for insured individuals with a high risk of hereditary breast cancer who meet the following criteria:

High Risk Criteria - the individual must meet at least one of these criteria:

- Two or more first-degree relatives with breast cancer
- One first-degree relative and two or more second-degree or third-degree relatives with breast cancer
- One first-degree relative with breast cancer before the age of 45 years and one other relative with breast cancer
- One first-degree relative with breast cancer and one or more relatives with ovarian cancer
- Two second - degree or third-degree relatives with breast cancer and one or more with ovarian cancer
- One second-degree or third-degree relative with breast cancer and two or more with ovarian cancer
- Three or more second-degree or third-degree relatives with breast cancer
- One first-degree relative with bilateral breast cancer
- Presence of a BRCA1 or BRCA2 mutation in the individual consistent with a BRCA1 or BRCA2 mutation in a family member with breast or ovarian cancer.
- Presence of a p53 mutation (Li-Fraumeni syndrome), or PTEN mutation (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), in the individual or a first degree relative
- For individuals with biopsies showing lobular carcinoma in situ (LCIS) or who are at high risk for breast cancer related to having a previous carcinoma in one breast.
- History of exposure or treatment with thoracic radiation before the age of 30

MP065 Obesity Surgery - REVISED – (Added Exclusions)

EXCLUSIONS: The following surgical interventions are considered investigational and are **NOT COVERED.**
There is insufficient evidence in the published, peer-reviewed medical literature to support the use of bariatric surgery as a treatment for the primary diagnosis of gastroparesis, infertility, gastroesophageal

reflux, or diabetes members with a BMI of less than 35. Use of bariatric procedures as treatment of these conditions is considered **experimental, investigational or unproven**, and therefore, **NOT COVERED.**

There is insufficient evidence in the published, peer-reviewed medical literature to support the use of space-occupying balloon inserts as a treatment for obesity. Use of this bariatric procedure is considered experimental, investigational or unproven, and therefore, **NOT COVERED**.

MP072 Perc Disc Decomp. Nucleoplasty - REVISED – (Revised policy; combined related policy)

DESCRIPTION:

Percutaneous manual disc decompression utilizing a cutting forceps or automated mechanical intervertebral disc decompression utilizing a Stryker Dekompressor® (a.k.a. Automated Percutaneous Nucleotomy) or SpineJet hydrodiskectomy involves placement of a probe within the intervertebral disc under image guidance with mechanical aspiration of disc material using a suction cutting device. ~~is considered **medically necessary** for individuals who have physical and diagnostic imaging evidence that a single lumbar disc has an uncomplicated herniation that is contained within the annulus~~.

Laser discectomy is a minimally invasive alternative to open surgical or mechanical methods of disc decompression for the treatment of symptomatic intervertebral disc herniation that has not responded to conservative therapy. The primary goals of laser discectomy are to relieve intractable back pain and/or neuropathy and allow return to normal activities

Percutaneous disc decompression using low-temperature, localized, radiofrequency energy (DISC Nucleoplasty™) is a minimally invasive surgical volumetric reduction of the nucleus pulposis utilizing Coblation technology to ablate or remove tissue as a treatment for discogenic back pain.

INDICATIONS:

Percutaneous manual disc decompression utilizing a cutting forceps or automated mechanical intervertebral disc decompression utilizing a Stryker Dekompressor® (a.k.a. Automated Percutaneous Nucleotomy) or SpineJet hydrodiskectomy is considered medically necessary for members who have physical and diagnostic imaging evidence that a single lumbar disc has an uncomplicated herniation that is contained within the annulus.

Percutaneous laser lumbar discectomy is considered medically necessary for members who have physical and diagnostic imaging evidence that a single lumbar disc has an uncomplicated herniation that is contained within the annulus and in which a well-managed course of conservative therapy (defined as medication and physical therapy) has failed to relieve pain and other signs and symptoms, therefore, making the individual a candidate for invasive treatment

For Medicare Business Segment

Percutaneous Image-guided Lumbar Decompression(PILD) is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This is a procedure proposed as a treatment for symptomatic Lumbar Spinal Stenosis (LSS) unresponsive to conservative therapy. This procedure is generally described as a non-invasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram. The Centers for Medicare & Medicaid Services (CMS) has determined that PILD will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through Coverage with Evidence Development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269

See MP263 Minimally Invasive Lumbar Decompression (MILD) and Percutaneous Image-guided Lumbar Decompression (PILD)

EXCLUSIONS: The Plan does **NOT** provide coverage for Percutaneous disc decompression using low-temperature, localized, radiofrequency energy (DISC Nucleoplasty™) 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 any of the following because they are considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these treatments on health outcomes when compared to established treatments or technologies.

- Chemonucleolysis
- Intradiscal electrothermal annuloplasty (IDET) – See MP 30
- Microendoscopic discectomy (MED) procedure for decompression of lumbar spine stenosis, lumbar disc herniation, or other indications

MP098 Genetic Testing/Colorectal CA - REVISED – (Clarified Criteria)

INDICATIONS:

***REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION**

- Genetic testing to determine the carrier status of the adenosis polyposis coli (APC) gene when criteria are met. (See applicable medical criteria below)
- Genetic testing to determine the carrier status of the MutY homolog [MYH] when the member ~~insured individual~~ meets criteria (*See applicable medical criteria below)
- Genetic testing to determine the carrier status of the HNPCC gene when either the Amsterdam or Bethesda criteria is met. (*See applicable medical criteria below)

MEDICAL CRITERIA:

For APC gene testing for familial adenomatous polyposis (FAP) and Attenuated FAP (AFAP):

To determine carrier status of the adenomatous polyposis coli gene (APC) for familial adenomatous polyposis (FAP) or attenuated familial adenomatous polyposis (AFAP) in the following subjects:

1. Individuals with greater than ~~20~~ 10 adenomatous colonic polyps in their lifetime; OR
2. In first-degree relatives (e.g., siblings, parents, offspring) of an individual diagnosed with FAP or AFAP; OR
3. Personal history of desmoid tumor

For MutY human homolog [MYH]) gene testing for MYH-associated polyposis (MAP) :

MYH-associated polyposis (MAP) genetic testing (gene MutY human homolog [MYH]) is covered in ANY of the following situations:

- Confirmatory testing for individuals with a history of adenomatous polyposis (>10 adenomas) and negative APC mutation testing: **or**
- For predictive testing when an individual has a sibling with known MYH polyposis; **or**
- For predictive testing when an individual has at least one affected sibling with findings consistent with recessive inheritance (i.e., MAP)

For HNPCC; Lynch Syndrome genetic testing (gene MLH1, MSH2, MSH6, PMS2, EPCAM):

NOTE: COLARIS Test® is a patented test for assessment of colorectal cancer risk. It detects mutations in MLH1, MSH2, PMS2 and EPCAM genes. COLARIS AP detects mutations in the APC and MYH genes.

The member ~~insured individual~~ must meet either criteria set:

Microsatellite instability (MSI) Testing or immunohistochemical (IHC) Analysis
Microsatellite instability (MSI) testing or immunohistochemical (IHC) analysis of the tumor is considered medically necessary when any of the following criteria are met:

- Endometrial cancer diagnosed in a member less than 50 years of age
- Colorectal Cancer diagnosed in a ~~patient~~ member who is less than ~~50~~ 70 years of age
- Presence of synchronous, or metachronous Lynch Syndrome (LS)-associated tumors*, regardless of age
- Colorectal Cancer with the MSI-H histology diagnosed in a member at any age ~~an insured individual who is less than 60 years of age~~
- Colorectal Cancer diagnosed in a member ~~insured individual~~ with one or more first-degree relatives with an LS-related cancer, with one of the cancers being diagnosed under age 50 years
- Colorectal cancer diagnosed in a patient with two or more first- or second-degree relatives with LS-related cancers regardless of age

* Lynch syndrome-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestinal cancers, as well as sebaceous gland adenomas and keratoacanthomas.

COLOGUARD TESTING:

Fecal DNA Testing: (e.g., Cologuard,) **DOES NOT REQUIRE PRIOR AUTHORIZATION** a noninvasive, multitarget fecal DNA test for the qualitative detection of colorectal neoplasia-associated DNA markers in addition to the presence of occult hemoglobin in stool is covered as a preventive screening methodology once every 3 years according to the following criteria:

- Age 50 to 85 years; and
- Asymptomatic (no signs/symptoms including but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test, or fecal immunochemical test); and
- There has been no documentation of a normal colonoscopy in the previous 10 years; and
- At average risk of developing CRC defined as:
    - no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease including Crohn's disease and ulcerative colitis; and
    - no family history of colorectal cancer or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis CRC

~~**Microsatellite instability (MSI) Testing or immunohistochemical (IHC) Analysis**~~
~~Microsatellite instability (MSI) testing or immunohistochemical (IHC) analysis of the tumor is considered medically necessary when any of the following criteria are met:~~

- ~~Colorectal Cancer diagnosed in a patient who is less than 50 years of age~~
- ~~Presence of synchronous, or metachronous Lynch syndrome-associated tumors, regardless of age~~
- ~~Colorectal Cancer with the MSI-H histology diagnosed in an insured individual who is less than 60 years of age~~
- ~~Colorectal Cancer diagnosed in an insured individual with one or more first-degree relatives with an LS-related cancer, with one of the cancers being diagnosed under age 50 years~~
- ~~Colorectal cancer diagnosed in a patient with two or more first- or second-degree relatives with LS-related cancers regardless of age~~

MP135 Osseointegrated Hearing Device - REVISED – (Added Exclusion)

EXCLUSIONS:

Osseointegrated hearing devices are excluded from coverage when qualifying criteria are not met.

The Plan does **NOT** provide coverage for the use of Intra-oral bone conduction hearing aids (e.g., the SoundBite hearing system) for the treatment of hearing loss 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 treatment on health outcomes when compared to established treatments or technologies.

MP150 Carotid Artery Stent - REVISED – (Revised Criteria)

INDICATIONS:

Coverage is limited to the use of FDA approved carotid stents ~~in percutaneous transluminal angioplasty of the carotid artery~~ for FDA approved indications when ~~furnished in accordance with FDA approved protocols~~ .the following criteria are met:

- Documented evidence of a reference vessel diameter within the range of 4.0mm and 9.0mm; **and**
- Member is at high risk* for carotid endarterectomy (CEA) with one of the following:
  - symptomatic carotid stenosis greater than 50% or more by angiogram or 70% or more by ultrasound; **or**
  - asymptomatic carotid artery stenosis of 60% or more by angiogram or 70% or more by ultrasound.

*CMS defines high risk as those “having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and who would be poor candidates for CEA in the opinion of a surgeon”. Significant comorbid conditions include but are not limited to:

•congestive heart failure (CHF) class III/IV;
•left ventricular ejection fraction (LVEF) < 30%;
•unstable angina;
•contralateral carotid occlusion;
•recent myocardial infarction (MI);
•previous CEA with recurrent stenosis ;
•prior radiation treatment to the neck; and
•other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Centers for Medicare and Medicaid Services Decision Memo for Carotid Artery Stenting (CAG-00085R0

- ~~Documented evidence of the following:~~
  1. ~~at high risk for carotid endarterectomy with symptomatic carotid stenosis greater than 50%;~~

  ~~**OR**~~

  2. ~~at high risk for carotid endarterectomy with asymptomatic carotid artery stenosis of 80% or more.~~

  ~~**AND**~~

  - ~~The provider must meet the procedural requirements for competency as required by the **ACC/ACP/SCAL/SVMB/SVS Clinical Competency Statement**[**]:~~

  1. ~~Overall carotid surgical experience~~
  2. ~~A minimum of 25 interventional (13 as the primary operator) carotid stent procedures using an FDA approved carotid stent.~~

~~* In August 2004, the US Food and Drug Administration (FDA) granted Pre Market Approval to Guidant Corporation's ACCULINK™ Carotid Stent System and the RX ACCULINK™ Carotid Stent System for the treatment of those at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the following criteria:~~

1. ~~Documented evidence of neurological symptoms and equal to or greater than 50% to 70% stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and equal to or greater than 80% stenosis.~~

2. ~~Documented evidence of a reference vessel diameter within the range of 4.0mm and 9.0mm.~~

MP204 Nasal and Sinus Surgery - REVISED – (Revised Criteria, Exclusion)

Balloon Sinuplasty:

Balloon sinuplasty when performed as a component of FESS, or as a stand-alone procedure is considered medically necessary when the following criteria are met:

- Recurrent frontal, maxillary or sphenoidal sinusitis refractory to conservative medical management (nasal lavage, corticosteroids, antibiotics, etc); and
- Chronic sinusitis is confirmed by imaging studies that show one or more of the following:
  - Mucosal thickening
  - Bone thickening or remodeling
  - Obstruction of the osteomeatal complex

➢ ~~The Geisinger Technology Assessment Committee has reviewed this device, and considers the use of the **balloon sinuplasty** device as medically necessary only when used as an adjunct tool in FESS procedures.~~

EXCLUSIONS:

Balloon Sinuplasty:

The Plan does **NOT** provide coverage for the use of balloon sinuplasty ~~as a stand-alone procedure~~ as a treatment for nasal polyposis, sinusitis with fungal disease, or if the sinus being treated has failed previous balloon dilation ~~because it is~~ Use of balloon sinuplasty for these conditions 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.

MP218 Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease - REVISED – (Revised Language)

DESCRIPTION:

The Prometheus system is a commercially available diagnostic system that uses combinations of tests for anti-neutrophil cytoplasmic antibody (ANCA) and/or anti- Saccharomyces cerevisiae antibody (ASCA) to aid in the diagnosis of Inflammatory Bowel Disease (IBD). Tests/test panels include, but are not limited to the following:

~~Promenteus~~ Prometheus® IBD Serology 7

MP232 Autism Spectrum Disorder Evaluation and Medical Management - REVISED – (Revised Language)

EVALUATION SERVICES:

The following services are considered medically necessary for children and adolescents under age 21 by the Child Neurology Society, American Academy of Neurology and/or the American Academy of Pediatrics for the evaluation of ASD:

MANAGEMENT SERVICES:

Physical Therapy, Speech Therapy and/or Occupational Therapy (limitations may be based on individual contract, or by state mandate).

Coverage for any of these therapies is considered medically necessary when all of the following criteria are met

- Physician provided documentation of a diagnosis of ASD according to the DSM-5; **and**
- Physician provided documentation of a physical, social or communicative impairment; **and**
- The therapy is provided by a healthcare provider who is appropriately licensed and is eligible to provide the service under the terms of the ~~insured individual~~ member's contract; **and**
- The ~~insured individual~~ member's progress is measured on an ongoing basis to assure that the objectives of the treatment plan are being met and refinements to that plan are made as appropriate; **and**
- The ~~insured individual~~ member's parent(s) or caregiver is fully engaged in participation and providing the support required by the treatment plan.

Physical Therapy, Speech Therapy and/or Occupational Therapy may be deemed to be not medically necessary if:

- The treatment plan results in a consistently negative impact on function or behavior; or
- The ~~insured individual~~ memberexhibits documented improvements in function and/or behavior that can be appropriately maintained in a less intensive or less structured program.

Applied Behavior Analysis (covered only for ~~insured individual~~ member eligible for state mandated services)

- Criteria for coverage will be managed by the Plan's behavioral health vendor and in accordance with the OMHSAS Bulletin Medical Necessity Guideline for ABA using BSC-ASD & TSS Services for Children & Adolescents with ASD issued Jan 13th 2017.

MP289 Dry Eye Syndrome - REVISED – (Revised Indications)

INDICATIONS:

Punctal Plugs and Punctoplasty

The Plan considers punctal plugs, standard punctoplasty by electrodessication or electrocautery medically necessary when the following criteria are met:

Autologous Serum Tears for the treatment of severe dry eye syndrome is considered to be medically necessary when

- The condition is refractory to non-prescription artificial tears; and
- A documented failure, intolerance or contraindication to commercially available pharmacologic therapies

MP259 Phototherapy for the Treatment of Dermatological Conditions - REVISED – (Revised Criteria)

Home Light Therapy Units: **Requires Prior Authorization by a Plan Medical Director or Designee**

Home light therapy will be covered if all of the following criteria are met:

1. The panel is requested by a dermatologist; and
2. The individual is under the requesting provider's supervision with regularly scheduled exams (patient is seen at least once a year); and
3. Treatment is expected to be ongoing or long term (e.g., greater than 4 months) ; and
4. The individual has a diagnosis of moderate-to-severe psoriasis and a therapeutic failure on, intolerance to, or contraindication to topical therapy; and
5. ~~The individual meets one of the following:~~
    a. ~~A trial of office based therapy has resulted in symptomatic improvement such that home based therapy has a high likelihood of being successful; **OR**~~
    b. ~~The patient has a history of response to natural UV light (i.e., psoriasis improves over the summer); **OR**~~
    c. ~~The individual is unable to attend office-based therapy due to a serious medical or physical condition such as, but not limited to:~~
        i. ~~Individual is homebound as defined by Centers for Medicare & Medicaid Services (CMS)*; or~~
        ii. ~~Leaving home requires special services; or~~
        iii. ~~Leaving home involves unreasonable risk; or~~
        iv. ~~Patient does not have reliable transportation for regular office visits; or~~
        v. ~~The closest clinic that offers office-based therapy is > 30 miles away~~
6. The panel size requested is appropriate for the affected area(s).

~~***30.1.1 - Patient Confined to the Home (Rev.172, Issued: 10-18-13, Effective: 11-19-13, Implementation: 11- 19 -13)**~~

~~An individual shall be considered "confined to the home" (homebound) if the following two criteria are met:~~
~~1.Criteria-One: The patient must either:~~

- ~~Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence; OR~~
- ~~Have a condition such that leaving his or her home is medically contraindicated.~~

~~If the patient meets one of the criteria in Criteria-One, then the patient must ALSO meet two additional requirements defined in Criteria-Two below.~~
~~2.Criteria-Two:~~

- ~~There must exist a normal inability to leave home; AND~~
- ~~Leaving home must require a considerable and taxing effort~~

~~**Confined to the Home Definition in Chapter 15, Covered Medical and Other Health Services, of the Medicare Benefit Policy Manual http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R192BP.pdf**~~

MP294 Intercostal Nerve Block - REVISED – (Revised Criteria)

INDICATIONS: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

Intercostal Nerve Block may be considered medically necessary when **one of the following criteria is met:**

1. Rib Fracture; **or**
2. Thorocotomy incision; **or**
3. Post-herpetic neuralgia; ~~**or**~~
4. ~~Other neuropathic process if **all of the following criteria are met:**~~
    - ~~Suspected organic problem; **and**~~

- ~~Lack of psychogenic origin;~~ ~~**and**~~
- ~~No evidence of acute infection of any type;~~ ~~**and**~~
- ~~Moderate to severe pain rating;~~ ~~**and**~~
- ~~Documented failure or contraindication to pharmacologic therapy. There must be documentation of the use of at least three (3) classes of medications from the following list of medication classes must be submitted for review: NSAIDs, opiates, non-opioid analgesics, anti-epileptic medications used for treatment of chronic pain, antidepressant medications used for treatment of chronic pain, ASA or ASA derivatives, muscle relaxants, steroids, such as prednisone or Medrol or documented contraindication to each of these drug classes~~.

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
MP040 Somnoplasty/ Coblation
MP049 Visual Field Testing
MP057 Prophylactic Oophorectomy
MP088 Perc. Laser Lumbar Discectomy
MP093 Uroleume
MP101 GliaSite Radiation Therapy
MP129 Total Parenteral Nutrition
MP131 VitalStim NMES
MP146 Sympathetic Therapy
MP154 Transanal Radiofrequency Therapy for Fecal Incontinence (Secca)
MP193 Microvolt T-wave Alternans
MP199 Corneal Pachymetry
MP213 Computerized Corneal Topography
MP228 HPV DNA Testing
MP229 Prolozone Therapy
MP250 Bronchial Thermoplasty
MP256 Transoral Incisionless Fundoplication
MP277 Vision Therapy/ Orthoptics
MP290 Fecal Microbiota Transplantation