"What's New" Medical Policy Updates June 2018

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, 2018** (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 Therapy – REVISED – (Added Indication)

Vein stripping, ligation, endovenous radiofrequency or laser ablation, excision, cyanoacrylate-based therapy (e.g., VenaSeal ™) or transilluminated powered phlebectomy of the great saphenous vein, small saphenous vein or both, or perforator veins, may be considered medically necessary when the following criteria are met:

MP004 Biofeedback – REVISED – (Added Indication; Edited Language)

INDICATIONS: Requires Prior Medical Director or designee Authorization for ~~insured individuals~~ members with specific benefit coverage that includes biofeedback training.

For Medicare Business Segment ~~and Medicaid lines of Business~~:

- Biofeedback is covered for the treatment and management of urinary incontinence (stress, urge, mixed) with documentation of failed pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

- Biofeedback therapy is covered under Medicare when it is reasonable and necessary for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful.

For Medicaid Business segment:

Biofeedback will be considered medically necessary for Medicaid members for any of the following indications:

- urinary incontinence
- migraine and tension-type headache
- anal spasm, incontinence of feces
- muscular wasting and disuse atrophy
- muscle spasm

For Commercial Lines of Business:
For contracts in which biofeedback is not specifically excluded, biofeedback will be considered medically necessary for any of the following indications:

- Migraine and tension-type headache
- Urinary incontinence (stress, urge, mixed) with documentation of failed pelvic muscle exercise (PME) training
- Anal spasm
- Incontinence of feces
- Muscular wasting and disuse atrophy
- Muscle spasm

LIMITATIONS:
There must be documentation in the ~~insured individual's~~ member's medical record to support the following:

1. The ~~insured individuals~~ members must be motivated to actively participate in the treatment plan.
2. The ~~insured individuals~~ members must be capable of participating in the treatment plan (both physically and intellectually).
3. The ~~insured individual's~~ member's condition can be appropriately treated with biofeedback and pathology does not exist to prevent success of the treatment.

MP054 Prophylactic Mastectomy – REVISED – (Added Indication; Edited Language)

Gail model: a breast cancer risk assessment algorithm using the following five risk factors: age at evaluation, age at menarche, age at first live birth, number of breast biopsies, and number of first-degree relatives with breast cancer.
Claus model: a breast cancer risk assessment algorithm used to predict the cumulative probability of disease in ~~individual~~ members based on a particular family history of breast cancer and known age of disease onset.

DESCRIPTION:
Prophylactic mastectomy is the removal of the breast in the absence of malignant disease in ~~insured individuals~~ members with significant risk factors for breast carcinoma.

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

High Risk Criteria - the ~~individual~~ member 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~~ member consistent with a BRCA1 or BRCA2 mutation in a family member with breast or ovarian cancer.
- Presence of a TP53 mutation (Li-Fraumeni syndrome), or PTEN mutation (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), in the ~~individual~~ member or a first degree relative
- For ~~individual~~ members 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
- Presence of PALB2, CDH1 or STK11 mutation in conjunction with family history of breast cancer. (Note: there are insufficient data to support risk-reducing mastectomy based on the presence of PALB2, CDH1 or STK11 mutation alone)

REQUIREMENT:
All ~~insured individuals~~ members considering a prophylactic mastectomy must undergo counseling regarding cancer risks from a genetic counselor. Cancer risk should be assessed by performing a complete family history, use of the Gail or Claus model to estimate the risk of cancer, and discussion of the various treatment options, including increased surveillance should be included in the consultation.

EXCLUSIONS:
Prophylactic mastectomy is considered **experimental, investigational, and unproven** for ~~insured individuals~~ members with atypical hyperplasia whose BRCA gene carrier status is unknown or negative and who does not have one of the above inclusion criteria.

MP057 Prophylactic Oophorectomy – REVISED – (Added Indication)

INDICATIONS:
Prophylactic bilateral oophorectomy may be considered medically necessary in selected patients, with other risk factors including null parity, low parity, infertility, early menarche, late menopause, and late first pregnancy, who have **ONE** of the following criteria:

1. Members with a known BRCA1 or BRCA2 mutation confirmed by molecular susceptibility testing.
2. Members who have completed childbearing years (usually age 40 years) and has hereditary ovarian cancer syndrome based on a family pedigree constructed by a physician or genetic counselor competent in determining the presence of an autosomal dominant inheritance pattern.
3. Members with a personal history of breast cancer and at least one 1st degree relative (e.g., mother, sister, daughter) with history of ovarian cancer.
4. Members with two 1st degree relatives (e.g., mother, sister, daughter) with a history of ovarian cancer.
5. Members with one 1st degree relative (e.g., mother, sister, daughter) and one or more 2nd degree relatives (maternal or paternal aunt or grandmother) with ovarian cancer.
6. Members with a known familial cancer syndrome associated with increased risk of ovarian cancer (e.g., hereditary nonpolyposis colorectal cancer [HNPCC], Lynch syndrome)

MP098 Genetic Testing/Colorectal CA – REVISED – (Criteria Update)

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 must meet either criteria set:**~~
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.

Hereditary non-polyposis colorectal cancer (HNPCC)/Lynch syndrome (LS): (MLH1, MSH2, MSH6, PMS2, EPCAM sequence analysis) gene testing is considered medically necessary for members who meet any one of the following criteria:
The member:

- is diagnosed with colorectal cancer with the MSI histology at any age; *or*
- is diagnosed with endometrial cancer before age 50 years; *or*
- meets Amsterdam or Revised Bethesda Guidelines; *or*
- is diagnosed with a synchronous, or metachronous Lynch Syndrome (LS)-associated tumors*, regardless of age; or
- has a 1st- or 2nd-degree relative with a disease confirmed to be caused by a HNPCC mutation (genes MLH1, MSH2, MSH6, PMS2, EPCAM); *or*
- has ≥5% risk of LS on a validated mutation prediction model (eg, MMRpro, PREMM, MMRpredict)
    - http://premm.dfci.harvard.edu/
    - http://hnpccpredict.hgu.mrc.ac.uk/.
    - http://www4.utsouthwestern.edu/breasthealth/cagene/.

* 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

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:
The member has:

- CRC diagnosed <70 yrs; or
- CRC diagnosed > 70 yrs and meets Bethesda guidelines; or
- endometrial cancer diagnosed before age 50 years

MSI testing or IHC analysis should be used as an initial test in members with colorectal or endometrial cancer to identify those who should proceed with HNPCC mutation analysis.

*__NCCN Guidelines v1.2017 Lynch Syndrome__: the panel recommends tumor testing with IHC and/or MSI be used as the primary approach for pathology-lab-based universal screening. If tumor is available, LS-specific testing or multi-gene testing without IHC or MSI should be utilized in select cases under direction of a clinician with expertise in genetics, and should not be used as a universal screening strategy.

~~**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 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 Colorectal Cancer diagnosed in a member 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.~~

MP135 Osseointegrated Hearing Device – REVISED – (Clarified Criteria)

Soft-Band
Children under the age of five may wear ~~the~~ a transcutaneous, non-surgical application of the BAHA device on a headband. The BAHA can be fitted onto a soft band as soon as the hearing loss has been diagnosed, thus reducing the effects of hearing deprivation. The soft band, used with the headband, work like the conventional bone conductor. A BAHA is worn on a soft band until the child is over the age of five as FDA approved and the implant surgery is scheduled.

MP150 Carotid Artery Stent – REVISED – (Added Criteria)

INDICATIONS:
Coverage is limited to the use of FDA approved carotid stents for FDA approved indications when the following criteria are met:

- Documented evidence of a reference vessel diameter within the range of 4.0mm and 9.0mm; **and one of the following:**
    - 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.

or

- Members who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201),

MP213 Computerized Corneal Topography – REVISED – (Refined Criteria)

INDICATIONS: Computerized Corneal Topography may be considered medically necessary for ANY of the following indications:

- Diagnosis and management of keratoconus, bullous keratopathy, corneal scarring, or corneal dystrophy;
- Complications post-corneal transplant
- Post-operative management of penetrating keratoplasty or cataract surgery;
- pterygium and/or corneal ectasia

~~- assessment of post-operative complications associated with post-traumatic corneal scarring or complications of a transplanted cornea;~~
~~- Diagnosis and management of keratoconus, bullous keratopathy, corneal scarring, corneal ectasia, or corneal dystrophy;~~
~~- Post-operative management of penetrating Keratoplasty or cataract surgery;~~
~~- Preoperative evaluation for phototherapeutic keratectomy.~~

EXCLUSIONS:
If the Plan does **NOT** provide coverage for any surgery to correct the refractive error of the eye, then the use of Computerized Corneal Topography would **NOT** be covered for the routine pre-operative or post-

operative evaluation of the cornea when associated with refractive surgeries (i.e. LASIK, radial Keratotomy).

There is insufficient evidence in the available published, peer-reviewed medical literature to support the use of Computerized Corneal Topography outside of the established indications listed above. Other uses of Computerized Corneal Topography ~~is~~ are considered experimental, investigational or unproven and ~~is~~ are **NOT COVERED**.

MP259 Phototherapy for the Treatment of Dermatological Conditions – REVISED – (Expanded 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 one of the following:
   ~~moderate-to-severe~~ psoriasis characterized by ≥ 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals, and a therapeutic failure on, intolerance to, or contraindication to topical therapy
   atopic dermatitis / Eczema
   Lichen planus;
   Localized scleroderma
   Chronic urticaria
   Severe pruritus
   Cutaneous T-cell lymphoma (e.g., mycosis fungoides)
   Vitiligo when it affects:
   a. the skin of the head and/or neck area, or,
   b. other body areas in excess of 30% of skin surface
5. The panel size requested is appropriate for the affected area(s).

MP273 Gene-based Testing and/or Protein Biomarkers for Diagnosis and Management of Prostate Cancer – REVISED – (Title Change)

MP321 Gene Expression Profiling for Cutaneous Melanoma – NEW

DESCRIPTION: Melanoma is an aggressive cancer that can be difficult to diagnose. Improved patient outcomes is attributed to Accurate and early diagnosis of melanocytic lesions. Histopathologic examination is adequate for most cases, however, approximately 15% of lesions are diagnostically challenging to diagnose by histopathology. In equivocal cases, members are at risk of receiving indeterminate or inaccurate diagnoses, leading to inappropriate treatment. Gene expression profiling is thought to provide additional clarity in these difficult to diagnose cases.

INDICATIONS: Gene expression profiling for cutaneous melanoma utilizing the myPath Melanoma is considered medically necessary when the following criteria are met:

- The lesion is considered to be a non-metastatic, melanocytic lesion that has not been previously treated, and
- Histopathology and clinical characteristics have not clearly differentiated the lesion as being benign or malignant, and
- The results of the gene expression testing will be used in conjunction with the clinical evaluation, histopathological features and other diagnostic procedures to determine and/or alter the treatment plan

EXCLUSIONS:
The Geisinger Technology Assessment Committee determined that at the present time, there is insufficient evidence in the peer-reviewed, published medical literature to support the use of DecisionDx Melanoma® for cutaneous melanoma Unless mandated by state or federal regulation, this testing is currently considered to be experimental, investigational or unproven, and therefore **NOT COVERED**.

MP088 Perc. Laser Lumbar Discectomy – (Retired)

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.

MP040 Somnoplasty/ Coblation
MP049 Visual Field Testing
MP065 Obesity Surgery
MP072 Perc Disc Decomp. Nucleoplasty
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
MP204 Nasal and Sinus Surgery
MP218 Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease
MP228 HPV DNA Testing
MP229 Prolozone Therapy
MP232 Autism Spectrum Disorder Evaluation and Medical Management
MP256 Transoral Incisionless Fundoplication
MP277 Vision Therapy/ Orthoptics
MP289 Dry Eye Syndrome
MP290 Fecal Microbiota Transplantation
MP294 Intercostal Nerve Block