"What’s New” Medical Policy Updates July 2019

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of June that will become effective August 15, 2019 (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) – (Added Indications)

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

For Medicare Business Segment
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.
- stress or urge incontinence
- fecal incontinence or constipation in selected patients with organic neuromuscular impairment

Per CMS Benefit Manual 10.5 -Joint Responses

A. BLS/ALS Joint Responses

In situations where a BLS entity provides the transport of the beneficiary and an ALS entity provides a service that meets the fee schedule definition of an ALS intervention (e.g., ALS assessment, Paramedic Intercept services, etc.), the BLS supplier may bill Medicare the ALS rate provided that a written agreement between the BLS and ALS entities exists prior to submitting the Medicare claim. Providers/suppliers must provide a copy of the agreement or other such evidence (e.g., signed attestation) as determined by their A/B MAC (A) or (B) upon request. A/B MACs (A) and (B) must refer any issues that cannot be resolved to the regional office.

Medicare does not regulate the compensation between the BLS entity and the ALS entity. If there is no agreement between the BLS ambulance supplier and the ALS entity furnishing the service, then only the BLS level of payment may be made. In this situation, the ALS entity’s services are not covered, and the
beneficiary is liable for the expense of the ALS services to the extent that these services are beyond the scope of the BLS level of payment.

MP065 Obesity Surgery – (Revised) – (Edited Indications and Exclusions)

1. Medical documentation of a diagnosis of morbid obesity that has persisted for a minimum of three years (two years for Medicaid business segment), which is supported by a minimum of semi-annual physician office acquired weights per year and
   a) Documented evidence of Class 3* obesity with a body mass index (BMI)** of forty (40) or greater with no co-morbidities (not applicable to Medicare. Surgical treatment for primary obesity is not a covered Medicare service); or
   b) Documented evidence of Class 2** obesity with a BMI of thirty-five (35) or greater with a diagnosis of at least one of the following comorbidities:
      • diabetes mellitus; or
      • obstructive sleep apnea diagnosed by polysomnography and requiring positive airway pressure (CPAP/BIPAP); or
      • biopsy proven non-alcoholic steatohepatitis (NASH); or
      • Coronary artery disease with documentation of previous myocardial infarction or angioplasty with stenting; or
      • Uncontrolled hypertension refractory to maximized doses of at least three (3) anti-hypertensive medications
      • Hyperlipidemia refractory to diet and maximum doses of lipid lowering medications (applicable to Medicare and Medicaid only)
      • Severe arthropathy of spine and/or weight-bearing joints (when obesity prohibits appropriate surgical management of joint dysfunction) (applicable to Medicare and Medicaid only)
      • Obesity-induced cardiomyopathy (applicable to Medicare and Medicaid only)
      • Hepatic steatosis without prior evidence of active inflammation (applicable to Medicare and Medicaid only)
      • Pseudotumor cerebri (documented idiopathic intracerebral hypertension). (applicable to Medicare and Medicaid only)

In 2016 the Center for Disease Control (CD) classified adult body mass index (BMI) for obesity as:
- Class 1 obesity is BMI 30 to 34.9
- ** Class 2 obesity is BMI 35 to 39.9
- *Class 3 obesity is BMI greater than or equal to 40

Note: BMI is calculated by Kg/M2 = [(Body weight in kilograms) divided by (height in meters)]²

And

2. Patient Member has failed¹ at least one physician-supervised² weight loss program lasting at least 4 months.

¹ failed= not losing and maintaining at least 20% reduction of highest weight
² physician-supervised programs may include:  
   • Physician visits addressing obesity or related co-morbidities
• LA Weight Loss™
• Physician’s Weight Loss®
• Weight Watchers®
• Other – upon review of program

And

3. The planned surgical intervention is one that is approved by the Plan based on evidence-based data regarding safety and outcomes. These include:
   • Roux-en-Y gastric bypass (open or laparoscopic)
   • Sleeve Gastrectomy (open or laparoscopic)
   • Biliopancreatic diversion with duodenal switch (BPD/DS)

*Note: Requests for adjustable laparoscopic banded gastroplasty will be evaluated on a “per case” basis.

4. Pre-Surgical Program:

   Insured individuals Members considering surgery must participate in at least a 6 month comprehensive program (consisting of at least a minimum of 6 visits over the 6 month timeframe within 12 months prior to surgery) in a facility designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (NBSQP) https://www.facs.org/quality-programs/mbsaqip. Facility participation in the Geisinger Bariatrics Proven Care® program will be considered in lieu of the designation as a Center of Excellence (COE) by NBSQP. This program must be physician-supervised and consist of dietary management, physical activity, psychiatric evaluation, medical management, behavior modification as well as social support. For more information, please view the following links:

   http://www.cms.hhs.gov/MedicareApprovedFacilitie/BSF/list.asp
   http://www.asbs.org/html/about/membersearch2.html

   And

5. The insured individual’s member’s diagnostic history does not display evidence of substance abuse, psychosis, eating disorders or uncontrolled depression within the past twenty-four (24) months, and

6. The insured individual member has stopped smoking for a minimum of two months (if applicable) prior to the requested surgery; and

7. The insured individuals Members who are prospective surgical candidates must have achieved full growth (18 years of age) before surgical intervention is considered; and

8. Surgery for morbid obesity must be performed in an institution designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (NBSQP) https://www.facs.org/quality-programs/mbsaqip. Facility participation in the Geisinger Bariatrics Proven Care® program will be considered in lieu of the designation as a COE by NBSQP. (Not Applicable to Medicare and Medicaid business segments eff. Sept 25, 2013 ) per http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Bariatric-Surgery.html

*Note: Requests for adjustable laparoscopic banded gastroplasty will be evaluated on a “per case” basis. Available data supports that this technology should be considered on in patients with a starting BMI of less than 46kg/m².*
**Note:** BMI is calculated by Kg/M²—[(Body weight in kilograms) divided by (height in meters)²]. See attached table.

**LIMITATIONS:**
Revision of bariatric surgery: **Bariatric surgery revision requires prior authorization**
Coverage is limited to one bariatric surgery per lifetime regardless of insurance carrier at the time of surgery with the following exception:

- Bariatric surgery revision will be considered for coverage **only** when requested as treatment for an associated medical complication such as, but not limited to obstruction, fistula or stricture for which no other treatment option is available, bowel perforation, band erosion or migration, or band failure. The revision must occur within a maximum of 16 weeks of the precipitating complication.

Inadequate weight loss due to individual noncompliance with postoperative nutrition and exercise recommendations is not a medically necessary indication for revision or conversion surgery and is not covered by the Plan.

Laparoscopic adjustable silicone gastric banding (LASGB) requests will be reviewed on a per-case basis and considered for coverage only by exception.

**For Medicare and Medicaid lines of Business:**
Original Medicare limits coverage of bariatric surgical interventions to procedures such as but not limited to, open and laparoscopic Roux-en-Y gastric bypass, Biliopancreatic Diversion with Duodenal Switch, open or laparoscopic sleeve gastrectomy, and laparoscopic adjustable gastric banding. Original Medicare considers open adjustable gastric banding; or open and laparoscopic vertical banded gastroplasty to be non-covered procedures. Therefore, these procedures will not be eligible for coverage for insured individuals enrolled in that line of business.

**EXCLUSIONS:** The following surgical interventions are considered investigational and are **NOT COVERED**.

- **Jejunoileal bypass** as a treatment for morbid obesity is considered **investigational**.
- **Gastric wrapping** as a treatment of morbid obesity is considered **investigational**.
- **Gastric balloon** is considered **investigational** since the long-term safety and efficacy of the device in the treatment of morbid obesity has not been established.
- **Open and laparoscopic vertical banded gastroplasty** as a treatment of morbid obesity is considered **investigational**

  * **NOTE:** Vertical-banded gastroplasty is eligible for coverage for Medicaid Business segment

- **Endoscopic Sleeve Gastroplasty** is considered investigational since the long-term safety and efficacy of the device in the treatment of morbid obesity has not been established.
- **Natural Orifice Transluminal Endoscopic Surgery™ (NOTES™)** (e.g., StomaphyX™)/endoscopic oral assisted procedures sleeve gastrectomy (SG) as a treatment for morbid obesity is considered investigational.
EXCLUSIONS:
In general, complementary and alternative therapies are considered to be experimental, investigational or unproven and are NOT COVERED (unless otherwise mandated under Act 62) because there is insufficient evidence in the published, peer-reviewed medical literature to support their safety and/or effectiveness. The list of such interventions includes, but is not limited to:

- Antineoplaston therapy
- Aromatherapy
- Ayurveda
- Art therapy *
- Apitherapy
- Bioidentical hormone therapy
- Biomagnetic therapy
- Chinese herbal medicine
- Colonic irrigation
- Cupping
- Dance/Movement therapy
- Di Bella Cancer Therapy
- Gemstone therapy
- Gerson therapy
- Greek cancer cure
- Guided imagery
- Herbal medicine
- Hippotheraphy
- Homeopathy
- Hoxsey method
- Humor therapy
- Sauna
- Psychodrama
- Polarity therapy
- Whole body vibration therapy
- Inversion therapy
- Intravenous vitamin C infusion
- Body wraps

**MP140 Automatic Implanted Defibrillator/CRT-D with Attachment – (Revised) – (Edited Indications for ICD/CRT)**

1. **Automatic Implantable Cardioverter-Defibrillator/ Cardiac Resynchronization Therapy Defibrillator (AICD/CRT)**

For members who are at high risk of sudden cardiac death secondary to ventricular arrhythmias, the combined AICD/CRT device is considered medically necessary when, in addition to either 1 or 2 above and any of the following criteria are also met:

- A documented cardiac arrest due to ventricular arrhythmia; **or**
- Documented, sustained ventricular tachyarrythmia (spontaneous or induced during an electrophysiology study), not associated with an acute myocardial infarction; **or**
- Documented familial or inherited conditions that carry a high risk of life threatening ventricular tachyarrythmia (e.g. long QT syndrome, Brugada syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia, or hypertrophic cardiomyopathy); **or**
MP141 Biventricular Pacemaker – (Revised) – (Expanded Coverage)

INDICATIONS:
Member must be under the care of, and the device be recommended by a cardiologist sub-specializing in electrophysiology.

Biventricular pacing/CRT is considered medically necessary for members who meet all of the following criteria:
- Moderate to severe congestive heart failure (New York Heart Assn. Functional Class II, III or IV)*; and
- Sinus rhythm, or chronic atrial fibrillation (AF), or frequent dependence on ventricular pacing; and
- Member remains symptomatic in spite of optimized pharmacotherapy; and
- Left ventricular ejection fraction of 35% or less; and
- QRS duration of 120 ms or greater

MP256 Transoral Incisionless Fundoplication – (Revised) – (Adopted Coverage)

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

COMMERCIAL BUSINESS SEGMENT
Transoral incisionless fundoplication is covered when all of the following criteria are met:
- Member is 18 years of age or greater; and
- A diagnosis of GERD has been established by endoscopy, ambulatory pH testing or barium swallow; and
- Member has a history of daily bothersome GERD symptoms inadequately controlled with individually maximized daily PPI use (unless intolerant to or contraindicated) for at least 6 months; and
- Documentation of gastroesophageal valve (Hill grade I – II) at gastroesophageal junction*; and
- Member has a BMI of 35 or less; and
- None of the following are present:
  - Hiatal hernia greater than 2 cm (unless simultaneous or prior repair of hiatal hernia is performed)
  - Esophagitis grade C or D **
  - Barrett’s esophagus greater than 2 cm
  - Esophageal ulcer, stricture or narrowing
  - Portal hypertension and/or varices
  - Active gastro-duodenal ulcer
  - Gastric outlet obstruction or stenosis
  - Gastroparesis
  - History of coagulation disorder, resective gastric or esophageal surgery, cervical spine fusion, Zenker’s diverticulum,

*Note: Hill Classification
1. Type I hernias are sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm. The stomach remains in its usual longitudinal alignment and the fundus remains below the gastroesophageal junction.
2. Type II hernias are pure paraesophageal hernias (PEH); the gastroesophageal junction remains in its normal anatomic position but a portion of the fundus herniates through the diaphragmatic hiatus adjacent to the esophagus.
3. Type III hernias are a combination of Types I and II, with both the gastroesophageal junction and the fundus herniating through the hiatus. The fundus lies above the gastroesophageal junction.
4. Type IV hiatal hernias are characterized by the presence of a structure other than stomach, such as the omentum, colon or small bowel within the hernia sac.


** Los Angeles (LA) Grading of Esophagitis

A. Mucosal break(s) ≤5 mm, without continuity across mucosal folds
B. Mucosal break(s) >5 mm, without continuity across mucosal folds
C. Mucosal break(s) continuous between ≥2 mucosal folds, involving <75% of the esophageal circumference
D. Mucosal break(s) involving ≥75% of the esophageal circumference


EXCLUSIONS:
The Plan does NOT provide coverage for Transoral Incisionless Fundoplication, including but not limited to the EndoGastric Solutions SerosaFuse™ implantable fasteners, and associated EsophyX delivery device, when the criteria for coverage are not met, 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.

MP306 Tumor Treatment Fields – (Revised) – (Edited Indication)

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

ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are NOT SEPARATELY REIMBURSABLE.

The Optune™tumor treatment field delivery system may be considered medically necessary when all of the following criteria are met:

1. As concomitant therapy with temzolomide in newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy; and
   - Member is an adult (defined by the FDA for this device as age 22 years or older); and
   - Karnofsky Performance Scale* score of 60-70 or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; and
   - Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day or

2. As a monotherapy for recurrent histologically- or radiologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain after receiving chemotherapy;
   - Member is an adult (defined by the FDA for this device as age 22 years or older); and
   - Karnofsky Performance Scale* score of 60-70 or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; and
   - Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day
DESCRIPTION: Molecular tests are specialized laboratory studies that evaluate human DNA, RNA, chromosomes, and/or the presence or absence of proteins whose production is mediated by specific genes. Molecular testing is divided into the following categories:

**Diagnostic testing (cancer):** Genetic testing for the purposes of confirming the presence or absence of cancer, and may contribute information to guide prognosis and treatment options. After treatment, active monitoring is often recommended to identify if the cancer is responding to treatment, has recurred or metastasized. Specific policies may apply. See also: *Genetic Testing for BRCA1/2; Genetic Testing Related to Colorectal Cancer; Gene Expression Profiling for Breast Cancer; Advanced Molecular Topographic Genotyping; Single Nucleotide Polymorphisms (SNPs) to Predict Risk of Non-Familial Breast Cancer; Microarray Gene Expression Testing for Cancer of Unknown Origin; Circulating Tumor Cells; Molecular Markers to Predict Thyroid FNA; Morphometric Tumor Analysis; Multi-gene Expression Assay for Predicting Recurrence in Colon Cancer; PCA3 and Gene Expression Assays for Prostate Cancer; Prolaris® Post-Prostatectomy Test; Proteomic Serum Analysis, Molecular Profiling of Malignant Tumors to Identify Targeted Therapies*

**Prenatal testing:** *Non-Invasive Testing for Fetal Aneuploidy and Microdeletions; Comparative Genomic Hybridization*

**Diagnostic testing (non-cancer):** identifies, confirms or rules out specific conditions of chromosomal or genetic etiology. Specific policies may apply. See also: *HPV DNA Testing; Janus Kinase 2 Gene Mutation Analysis; Gene Expression Testing to Predict Coronary Artery Disease; Whole Exome Sequencing*

**Carrier testing:** Genetic testing for the purposes of carrier screening is performed to identify genetic risk that may impact reproductive decision-making. Individuals identified as being “carriers” are typically not affected by the condition but have an increased risk of having a child with a genetic condition. Genetic testing for carrier screening may be available for autosomal recessive genetic conditions, X chromosome-linked conditions, and certain other chromosomal abnormalities.

**Prenatal testing:** detects abnormalities in a fetus’s genes or chromosomes that will result in a genetic mediated condition. Results of testing are used to guide reproductive decision-making, pregnancy management and anticipated management of the infant at birth. *Genetic Testing for Hereditary Disease Carrier Status*

**Predictive or pre-symptomatic testing:** detects genetic abnormalities that manifest in conditions later in life. Genetic test results may impact medical management through heightened screening strategies, preventive measures, and/or prophylactic medication. For newborn testing, state mandates apply. Specific policies may apply. See also: *Non-invasive Testing for Heart Transplant Rejection*

**Pharmacogenetic testing:** used to select appropriate treatments based on an individual’s likelihood of response or non-response, or risk of toxicity to a particular drug or therapy. Specific policies may apply. See also: *Chemosensitivity and Chemoresistance Assays; Pharmacogenetic Testing; Genotyping or Phenotyping for Thiopurine Methyltransferase*

**MP321 Gene Expression Profiling for Cutaneous Melanoma – (Revised) – (Expand Commercial and Medicare Coverage)**

INDICATIONS:

**COMMERCIAL AND MEDICARE BUSINESS SEGMENT:**

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.

**COMMERCIAL AND MEDICARE BUSINESS SEGMENT:**

Gene expression profiling for cutaneous melanoma utilizing the DecisionDx-Melanoma test is **considered medically necessary** when the following criteria are met:

- Patients diagnosed with pathologic stage sentinel lymph node biopsy (SLNB) eligible T1b and T2 cutaneous melanoma tumors with clinically negative sentinel node basins who are being considered for SLNB to determine eligibility for adjuvant therapy. (Per current NCCN and ASCO guidelines, SLNB eligible patients are defined as:
  - Patients with T1a tumors:
    - in whom there is significant uncertainty about the adequacy of microstaging (positive deep margin), or
    - with Breslow depth <0.8 mm and with other adverse features (eg. very high mitotic index [≥2/mm²], lymphovascular invasion, or a combination of these factors)
  - Patients with T1b tumors (≥0.8 mm or < 0.8 mm with ulceration)
  - Patients with T2 tumors

**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**.

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.

MP003 Ocular Photodynamic Therapy
MP045 Chest Percussion Vest
MP074 Interactive Metronome Training
MP084 Stereotactic Radiosurgery
MP089 Evaluation of Breast Ductal Lavage
MP110 Uterine Artery Embolization
MP121 Automated External Defibrillators
MP124 Transpupillary Thermotherapy
MP134 Gastric Electrical Stimulation
MP144 Vitamin B12 Injection Therapy
MP152 Low Level Laser Therapy
MP174 Exhaled Nitric Oxide for Asthma Management
MP203 Radiofrequency Ablation Therapy for Barrett’s Esophagus
MP216 Quantitative EEG (QEEG)
MP271 Non-Invasive Testing for Fetal Aneuploidy
MP299 Measurement of Serum Antibodies to Infliximab and Adalimumab