“What’s New” Medical Policy Updates September 2019

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of August that will become effective October 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.

MP098 Genetic Testing Related to Colorectal Cancer – (Revised) – (Added Exclusions)

EXCLUSIONS:
There is no evidence to support the use of genetic testing for individuals from the general population with average risk. This is considered NOT MEDICALLY NECESSARY.

The ColonSentry testing panel is considered experimental, investigational, or unproven and is NOT COVERED. There are no current evidence-based guidelines from medical professional organizations or public health agencies that recommend ColonSentry for colorectal cancer screening and no evidence to support the use of this testing.

For Commercial and Medicaid Business Segments: The Epi proColon test is considered experimental, investigational, or unproven and is NOT COVERED. 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.

For Medicare Business Segment: Epi proColon testing is covered as an alternative colorectal cancer screening strategy.

MP112 Wireless Capsule Endoscopy – (Revised) – (Added Smart Pill Coverage)

SmartPill® GI Monitoring System

For Commercial and Medicare Business segments:

SmartPill® GI Monitoring System may be considered medically necessary, as a diagnostic imaging tool when all of the following criteria are met:

1. To measure pressure, pH, transit time and temperature and assess gastric emptying time, colonic transit time, whole gut transit time in the evaluation of members with either:
   - chronic constipation; or
   - gastric dysmotility/ gastroparesis; or
   - evaluation of small bowel motility

   and

2. The absence of any of the following:
   - intestinal stricture
   - Inflammatory bowel disease
   - pacemaker

For Medicaid Business segment:
There is no coverage for this technology for the Medicaid business segment. Consideration through the Program Exception process may be requested if there is a clinical contraindication to the alternative diagnostic standards of care.

EXCLUSIONS:
Wireless capsule endoscopy is not intended for use as a gastrointestinal cancer-screening tool. This use is considered Not Medically Necessary and is **NOT COVERED**.

Wireless capsule endoscopy is Not Medically Necessary and **NOT COVERED** for the confirmation of lesions or pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum).

The Plan does **NOT** provide coverage for the use of a wireless capsule for measuring gastric emptying (SmartPill® GI Monitoring System) for all indications including but not limited to gastroparesis because it is considered experimental, investigational or unproven. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this testing on health outcomes when compared to established technologies.

**MP148 Ambulatory Cardiac Event Monitors – (Revised) – (Added Exclusion)**

EXCLUSIONS:
MCOT is considered experimental, investigational or unproven when used as a screening tool, and is **NOT COVERED**.

MCOT in excess of one unit (one to 30 consecutive days) is **NOT COVERED**.

The following cardiac monitoring systems including but not limited to:

- BIOTRONIK biomonitor
- smartphone ECG systems (eg, AliveCor, ViSi Mobile Monitoring System, Kardia Mobile, iHEART, CardioPatch etc.)

**MP183 Cranial Electrotherapy Stimulation – (Revised) – (Added Exclusions)**

EXCLUSIONS: The Plan does **NOT** provide coverage for Cranial Electrotherapy Stimulation of the brain as a treatment for any indication including but not limited to the treatment of anxiety, stress related conditions, depression, headache, substance abuse and cognitive dysfunction because it is considered experimental, investigational or unproven. Although the device is FDA approved, 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.

The Plan does **NOT** provide coverage for at home neuro-stimulation therapy (i.e. Fisher Wallace Stimulator) for any indication because it is considered experimental, investigational or unproven. Although the device is FDA approved, 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.

The Plan does **NOT** provide coverage for transcutaneous supraorbital nerve stimulation (t-SNS), neuromodulation or external trigeminal nerve stimulation (e-TNS), with the Cefaly Prevent, Cefaly Acute, and Cefaly Dual.) for any indication 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.
The Plan does NOT provide coverage for the use of auricular electrostimulation, including but not limited to the BRIDGE and the Drug Relief® Devices for opioid withdrawal, P-stim, E-Pulse, or ANSiStim devices for any indication 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.

**MP247 Nutritional Supplements – (Revised) – (Added Indication and Exclusion Language)**

**LOW-PROTEIN MODIFIED FOOD PRODUCTS**
Low-protein modified food products are specially formulated to have less than 1 gram of protein per serving. Low-protein modified food products are intended for use under the direction of a physician for the dietary treatment of hereditary metabolic diseases, but does not include a natural food that is naturally low in protein. Some examples of low-protein food products that are commercially available for purchase are breads, pasta, pastry shells, and rice pizza shells.

**Medicaid Business Segment:**
Oral or enteral nutrition products or supplements used for the treatment of members with an established diagnosis of inborn error of metabolism (eg, phenylketonuria (PKU) homocystinuria, branch chain ketonuria, galactosemia, etc) with documentation of failure of conservative dietary interventions are covered as mandated by Act 191.

**Oral Nutritional Products:**
For members under age 21 years:
Each case will be determined based on medical necessity. Physician documentation must provide all of the following:

- a description of the member’s clinical condition that clearly outlines why the nutritional needs cannot be met through dietary modification to increase caloric intake (snacks, higher calorie/protein foods)
- A description of the member’s current nutritional status (eg, height, weight, percentiles for pediatric members)
- A prescription or order including the product, administration route and rate of intake
- An estimated duration of therapy
- For oral nutritional supplementation expected to be required long term (months), documentation of a nutritional assessment needs to be provided that includes an assessment of current caloric intake, caloric needs, and why dietary modification cannot meet those needs.

**Pasteurized Human Donor Breast Milk**
Requests for pasteurized human donor breast milk will be reviewed using the American Academy of Pediatrics guidelines: [http://pediatrics.aappublications.org/content/pediatrics/139/1/e20163440.full.pdf](http://pediatrics.aappublications.org/content/pediatrics/139/1/e20163440.full.pdf)

- Donor human milk may be used for high-risk infants when the mother’s milk is not available or the mother cannot provide milk. Priority will be given to providing donor human milk to infants <1500 g birth weight.
- The donor must be identified and screened using methods such as those currently used by HMBANA milk banks or other established commercial milk banks.
- The donor milk is pasteurized according to accepted standards.
For members age 21 years and older:
Commercial oral nutrition products are covered if such products constitute 50% or more of total patient caloric intake and are found to be medically necessary. The following criteria must be met:

- Member must have a documented medical condition that limits his or her ability to ingest, digest, or absorb regular food; and
- reversible causes have been ruled out; and
- nutritional assessment has been completed to document current caloric intake, caloric needs, and why dietary modification cannot meet those needs

Enteral Nutrition:
Enteral Nutrition (including administration, supplies and formula) when ordered by a registered dietician, gastroenterologist or bariatrician may be considered medically necessary in members with:

Requirement of a feeding tube; and

a. Central nervous system injury or disease that results in partial or total inability to take nutrients orally and with functional gastrointestinal tract of sufficient absorptive capacity; or

b. Disease or injury (permanent or temporary) that requires the use of a feeding tube in members:
   i. Who are malnourished or are at risk of becoming malnourished; and
   ii. Who have inadequate or anticipated inadequate oral intake for at least 7 days; and
   iii. In whom the tube feeding provides the primary source of nutrition

c. Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)

A limit of 960 units per month equating to 96,000 calories per month, or 3,000 calories per day, for 32 days, which will meet the daily caloric needs of the vast majority of members will be considered medically necessary. However, if needed, an exception of the limits may be requested. A one-month supply will be provided each 32 days.

Amino acid-based Elemental formula may be considered to be medically necessary in members age 21 years and younger when all of the following criteria are met:

- Medical record documentation of a laboratory or diagnostic test supported diagnosis of one or more of the following:
  a. Short gut syndrome
  b. IgE mediated allergies to food proteins
  c. Food protein induced enterocolitis syndrome
  d. Eosinophilic esophagitis (EE)
  e. Eosinophilic gastroenteritis (EG)
  f. Eosinophilic colitis
  g. Amino acid, organic acid and fatty acid metabolic and malabsorption disorder
  h. Cystic fibrosis

and

- Documentation of at least two failed formula alternatives

LIMITATION:
Standard formula for newborns or infants is not considered to be medically necessary and is therefore not covered. Standard infant formula for normal infants or for infants with medical illness or disability is considered to be non-medical in nature, as nutrition is a normal need for all infants.

EXCLUSIONS:
Commercial Business Segment:
Oral nutrition products and/or supplements not used to treat inborn errors of metabolism are NOT COVERED including, but not limited to:
- Formula or Supplements to treat a deficient diet or to provide an alternative source of nutrition in conditions such as, but not limited to, allergies, obesity, hypo- or hyper-glycemia and gastrointestinal disorders; or
- Lactose-free foods; or
- Banked breast milk; or
- Standardized or specialized infant formulas (including over-the-counter infant formulas (such as Similac, Enfamil, etc.))

Grocery items and food additives as defined under section V. Additional Definitions or medical food products are NOT COVERED.

Enteral products for the diagnosis of “failure to thrive” are NOT COVERED.

Enteral products for the purpose of augmenting normal dietary sources of nutrition are NOT COVERED.

Digestive enzyme cartridges (e.g. Relizorb) used in conjunction with enteral nutrition therapy is considered to be of unproven benefit and therefore not medically necessary and NOT COVERED. 

NOTE: May be considered on a per-case basis through the Program Exception process for Medicaid Business segment members ages 5 years and older with exocrine pancreatic insufficiency who are partially or completely unable to hydrolyze fats in enteral formula.

Low-protein modified food products are NOT COVERED for inherited errors of metabolism because they do not meet the policy definition of medical foods or nutritional formulas. This information is in accordance with the state mandate.

MP267 Amniotic Membrane Transplantation – (Revised) – (Added Indication and Exclusion Language)

DESCRIPTION:
Amniotic membrane transplantation (AMT) is a procedure that utilizes amniotic membrane tissue to reconstruct damaged ocular surfaces and promote healing of corneal, conjunctival, and eyelid tissues after injury due to trauma, disease, or surgery. Human amniotic membrane grafts may also be used to treat lower extremity diabetic skin ulcers.

INDICATIONS:
Preserved human amniotic membrane transplantation may be considered medically necessary for the treatment of ocular surface defects including, but not limited to:
- Bullous keratopathy
- Chemical or thermal burns to ocular surface
- Corneal ulcerations
- Pterygium (either primary and/or recurrent)
- Stevens-Johnson syndrome
- Limbal cell deficiency
- Persistent epithelial defects
- Conjunctival surface reconstruction
- Herpes zoster ophthalmicus
Human amniotic membrane grafts will be considered medically necessary for the treatment of non-healing lower-extremity diabetic skin ulcers. (See also: MP075) Examples of these human amniotic membrane products include, but are not limited to:

- AmnioBand® Membrane
- Biovance®
- Epifix®
- GrafixCore™
- GrafixPrime™

**EXCLUSIONS:** Injection of human amniotic fluid is considered investigational for all indications including, but not limited to osteoarthritis and plantar fasciitis. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this service on health outcomes when compared to established treatments or technologies, and therefore are considered to be **NOT COVERED**.

**MP279 Gene Expression Testing to Predict Coronary Artery Disease – (Revised) – (Revised Criteria)**

**FOR MEDICARE and MEDICAID BUSINESS SEGMENT:**

Palmetto GBA, a national contractor that administers Medicare benefits has determined that the Corus® CAD (coronary artery disease) test (CardioDx, Inc., Palo Alto, CA) is considered reasonable and necessary for the evaluation of patients presenting with typical and atypical symptoms suggestive of coronary artery disease (CAD), members with stable symptoms that have a history of chest pain, suspected anginal equivalent to chest pain, or a high risk of CAD, but no known prior myocardial infarction or revascularization procedures.

**LIMITATIONS:** This test is not intended for use in patients with diabetes; known previous MI or revascularization procedures; in patients currently taking steroids, immunosuppressive agents or chemotherapy.

Per the Novitas Solutions LCD Corus® CAD Test (L36713), the following limitations apply:

1. The Corus® CAD test is considered not reasonable and necessary for members who are currently taking steroids, immunosuppressive agents, or chemotherapeutic agents or for members with:
   - acute or previous myocardial infarction;
   - high-risk unstable angina;
   - a history of obstructive CAD;
   - a previous revascularization procedure;
   - a history of a previous invasive procedure to open a blocked or narrow artery;
   - systemic infectious or systemic inflammatory conditions; or
   - diabetes.

2. The Corus® CAD test is considered not reasonable and necessary when used for any of the following:
   - to be used to screen for stenosis among members who are asymptomatic and not considered at high-risk for CAD;
   - to predict or detect response to therapy, or
   - to help select the optimal therapy for members.
MP292 Sympathetic Nerve Block – (Revised) – (Added Exclusion)

EXCLUSIONS:

- The Plan does NOT provide coverage for the use of sphenopalatine ganglion block in the treatment of headache or non-headache facial pain because it is considered experimental, investigational or unproven. Although the catheters used to administer the anesthetic agent are FDA approved, 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 (See MP318).

MP327 Autonomic Testing – (NEW)

DESCRIPTION: Autonomic testing is a battery of tests that evaluates the sympathetic, parasympathetic, and enteric nervous system. This policy focuses on the standard tests of sudomotor (sympathetic cholinergic), cardiovagal (parasympathetic) and sympathetic adrenergic system function:
- Cardiovagal function (heart rate variability, response to deep breathing and Valsalva)
- Vasomotor adrenergic function (blood pressure response to standing, Valsalva, and hand grip, tilt table testing)
- Sudomotor function (QSART, QST, TST, silastic sweat test)

Autonomic testing is an integral component of the clinical evaluation of members with autonomic disorders.

INDICATIONS: Autonomic testing is considered medically necessary in the evaluation of any of the following conditions:
- Diagnose the presence of autonomic neuropathy when signs or symptoms suggest a progressive autonomic neuropathy, including, but not limited to:
  - Diabetic neuropathy
  - Amyloid neuropathy
  - Sjögren's syndrome
  - Idiopathic neuropathy
  - Pure autonomic failure
  - Multiple system atrophy
- Evaluate orthostatic hypotension in a member with dizziness, a drop in blood pressure, or syncope upon standing
- Differentiate certain complicated variants of syncope from other causes of loss of consciousness.
- Evaluate the severity and distribution of a diagnosed progressive autonomic neuropathy.
- Diagnose and differentiate the cause of postural tachycardia syndrome.
- Evaluate change in type, distribution or severity of autonomic deficits in members with autonomic failure.
- Diagnose axonal neuropathy or suspected autonomic neuropathy in the symptomatic member
- In central neurodegenerative disorders, especially the synucleinopathies, distinguish multiple system atrophy from Parkinson's disease and diffuse Lewy body disease.

EXCLUSIONS:
Autonomic testing using automated devices, in which software automatically generates an interpretation, has not been validated (e.g., ANSAR ANX 3.0, SUDOSCAN, or electrochemical skin conductance [ESC]). There is insufficient evidence in the published, peer-reviewed medical literature to support the use of these devices. They are therefore considered to be experimental, investigational or unproven and NOT COVERED.
There is insufficient evidence in the published, peer-reviewed medical literature to support the use of autonomic testing in any of the following. The use of autonomic testing for these conditions is considered to be experimental, investigational or unproven and therefore **NOT COVERED**.

- Myofascial pain syndrome/fibromyalgia
- Raynaud’s phenomenon
- Predicting foot ulcers
- Flushing syndrome
- Chronic fatigue syndrome
- Generalized hyperhidrosis
- Palmoplantar hyperhidrosis
- Irritable bowel syndrome
- Somatization disorder
- Anxiety disorder

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.

- MP102 Morphometric Tumor Analysis
- MP151 Epidural Steroid Injection
- MP163 Thermography
- MP175 Trigger Point Injections
- MP185 Chemosensitivity and Chemoresistance Assays
- MP200 Osteochondral Autograft Transplant
- MP202 Interferential Stimulation
- MP206 Electrocardiographic Body Surface Mapping
- MP208 Selective Internal Radiation Therapy
- MP221 Suprachoroidal Delivery of Pharmacologic Agents
- MP234 Occipital Nerve Stimulation
- MP246 Multigene Expression Assay for predicting Recurrence in Colon Cancer
- MP283 Facet Injections
- MP287 Shift Care
- MP291 TX1 Tissue Removal System for Ablating and Removing Tissue
- MP295 Sacroiliac Joint Injection
- MP296 Occipital Nerve Block
- MP297 Suprascapular Nerve Block
- MP322 Drug Testing in Substance Abuse Treatment