“What’s New” Medical Policy Updates April 2024

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of March that will become **effective May 15, 2024** (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within members 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.

MP068 Reduction Mammaplasty – Revised – Add Cross Reference

CRITERIA:
For those members enrolled in product lines in which reduction mammaplasty for the treatment of complications secondary to macromastia is not specifically excluded, the following criteria will be used to determine eligibility for coverage.

a Physician provided documentation of a diagnosis of macromastia; **and**
b Severe chronic skin breakdown unresponsive to medical management; **or**
c Documented chronic pain due to macromastia defined by **all** of the following criteria
- Pain that affects the activities of daily living for a minimum of 6 months
- Documentation in the medical record to involve one of the following:
  - Upper back pain and/or
  - Neck/shoulders pain
  - Acquired kyphosis on X-ray due to weight of the breasts
  - Upper extremity parasthesia
  - Ulceration or pain/grooving from cutting of bra straps

and

c For members 40 years of age or older, a mammogram that was negative for cancer has been completed within the year prior to the planned reduction mammaplasty;

and

d Average weight of tissue planned to be removed in each breast, is above the 22nd percentile* on the Modified Schnur Sliding Scale based on the patient’s body surface area (BSA)**. (See Attachment A for Listing)

**To calculate body surface area (BSA):

$$BSA\ (m^2) = ([height\ (cm) \times weight\ (kg)]/3600)^{½}$$

*NOTE:
If the proposed total grams of tissue is less than the 22nd percentile but greater than the 5th percentile on the Modified Schnur scale, clinical documentation of circumstances to support the proposed tissue removal must be submitted for determination of medical necessity.

If the proposed total grams of tissue is less than the 5th percentile on the Modified Schnur scale, the procedure will be considered to be cosmetic and therefore **NOT COVERED.**

For treatment of gynecomastia, see **MP055 Mastectomy for Gynecomastia.**

For the treatment of gender dysphoria, see **MP307 Gender Dysphoria and Gender Confirmation Treatment**

MP106 Ultrasound/ Pregnancy – Revised – Add Exclusion

EXCLUSIONS:
Ultrasound examinations performed solely to satisfy a request to know the fetal sex, to view the fetus, or to obtain a picture of the fetus are not considered medically necessary.

The routine use of three-dimensional (3D) and four-dimensional (4D) fetal ultrasounds is considered unproven because of a lack of evidence that 3D and 4D ultrasounds alter management and improve clinical outcomes over standard two-dimensional (2D) ultrasounds.

MP136 Alternative or Complementary Medicine Therapies – Revised – Add Exclusion

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
Hippotherapy
Homeopathy
Hoxsey method
Humor therapy
Sauna
Psychodrama
Polarity therapy
Whole body vibration therapy
Inversion therapy
Intravenous vitamin C infusion
Body wraps
Wilderness Therapy
Brainspotting
Hydrazine sulfate
Hydrogen peroxide therapy
Hydrotherapy* (eg, spa therapy, water cure, etc.)
Livingston-Wheeler therapy
Magnet therapy
Mistletoe extract
Moxibustion
Music therapy*
Polarity therapy
Purging
Qigong
Reflexology
Reiki
Revici's guided chemotherapy
Rolfing
Shark cartilage products
Therapeutic touch
Yoga
Exercise With Oxygen Therapy (EWOT)
Transcendental meditation
Electrodermal stress analysis
Primal therapy
Pilates
Ozone therapy
Insulin potentiation therapy
Intravenous micronutrient therapy (Myers' Cocktail)
Bee sting therapy
Placentophagy
Emotional Freedom Technique (aka, EFT, Tapping)
Kambo Cleanse Therapy

MP158 Continuous Passive Motion – Revised – Add Exclusion

EXCLUSIONS:

The Plan does **NOT** provide coverage for any joint not listed under "Indications" 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 rehabilitative devices with remote adjustment and/or remote monitoring capability (e.g., ROMTech PortableConnect® Adaptive Telemed Technology). It is considered to be unproven due to the lack of scientific evidence of effects on health outcomes. 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.

MP176 Meniett Device – Revised – Added Language

DESCRIPTION:
The Meniett™ Device (e.g. Transtympanic Micropressure), an aural low-pulse pressure generator, is used to deliver low frequency, low-amplitude pressure pulses to the middle ear through a close fitting ear cuff and a previously placed tympanostomy tube. Although the precise mechanism of the Meniett™ Device is unknown, it is hypothesized that the transmission of the pulses to the inner ear promotes the flow of the endolymph out of the cochlea, which alleviates the hydrops and relieves symptoms. The treatment is self-administered three times daily, consisting of 3 cycles (1 minute of pressure pulses and 40 seconds of pause) per treatment. Each treatment lasts approximately 5 minutes, and an entire month of daily treatment is needed to determine if it is appropriate for the patient.

EXCLUSIONS: The Plan does **NOT** provide coverage for use of an aural low-pulse pressure generator (e.g. Transtympanic Micropressure) (i.e. Meniett™ Device) as a treatment for Meniere's disease 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.

MP201 Obstructive Sleep Apnea – Revised – Expand HNS Coverage

A. *Hypoglossal Nerve Stimulation*
Hypoglossal nerve stimulation using an FDA-approved device is considered medically necessary for the treatment of obstructive sleep apnea when ALL of the following criteria are met:

~~1.~~ The member is 22 years of age or older~~: and~~; **OR**
2. The member is between 18 and 22 years of age and one of the following is met:
   a. Member has had an adenotonsillectomy; or
   b. An adenotonsillectomy is contraindicated for the member.

and

MP204 Nasal and Sinus Surgery – Revised – Add Indication

Surgical Repair of Nasal Valve Collapse:
Surgical Repair of Nasal Valve Collapse utilizing cartilage grafts to support the existing cartilage in the lateral nasal wall or alar rim is considered medically necessary when the following criteria are met:

- Clinical documentation of one or more of the following:
  - Internal valve collapse or compromise of the upper lateral cartilage; **or**
  - External nasal valve compromise due to collapse of the lower lateral cartilage;

and

- Obstruction improves with one of the following:
  - the Cottle maneuver; or
  - or lateralization of the upper lateral cartilage from inside the nose with a nasal speculum; or
  - trial of external stents (e.g., Breathe Right nasal strips); or
  - trial of nasal dilators(e.g., Max-Air Nose Cones)

MP239 Pharmacogenetic Testing – Revised – Add Indications; Add Exclusions

INDICATIONS:
Pharmacogenetic testing is considered to be medically necessary when the identification of a specific gene marker is noted to be clinically necessary before initiation of therapy by the U.S. Food and Drug Administration as noted in the Indications section of the prescribing information and/or supported by NCCN Guidelines. Examples include, but are not limited to any of the following:

- ABCG2 for rosuvastatin (Crestor)
- ALK for crizotinib (Xalkori) or ceritinib (Zykadia)
- ALK for crizotinib (Xalkori), alectinib (Alecensa) or ceritinib (Zykadia) for the treatment of non-small cell lung cancer (NSCLC).
- BCR/ABL1 for dasatnib, imatinib, nilotinib, ponatinib and/or bosutinib
- BRAF and NRAS for cetuximab (Erbitux) or panitumumab (Vectibix).
- BRAF for vemurafenib (Zelboraf), dabrafenib (Tafinlar), pembrolizumab (Keytruda) or encorafenib (Braftovi)
- BRCA for olaparib (Lynparza), rucaparib (Rubraca)
- CACNA1S for volatile anesthetics
- CTFR for ivacaftor (Kalydeco) or lumacaftor/ivacaftor (Orkambi)
- CYP2B6 for efanvirenz (Sustiva)
- CYP2C19 for clopidogrel (Plavix) {**May be considered for program exception for the Medicaid business segment for this indication ~~as noted below~~}** Antidepressants, Barbiturates, Proton pump inhibitors, Mephenytoin
- CYP2C9 for warfarin metabolism, Celebrex, Marinol, Balversa, Ansaid, Cerebyx, Mobic, Dilantin, Feldene, Mayzent
- CYP2D6 for tetrabenazine (Xenazine) greater than 50 mg per day, eliglustat (Cerdelga), deutetrabenazine
  (austedo) greater than 36mg/day, Antidepressants for treatment of depression (including SSRI's) , Anti-psychotics for treatment of schizophrenia, atomoxetine, codeine, ondansetron, tropisetron, tamoxifen, tramadol, hydrocodone
- CYP3A5 for tacrolimus (Prograf, Protopic)
- CYP4F2 for warfarin
- DYPD gene mutation for capecitabine or 5-fluorouracil
- EGFR for cetuximab (Erbitux), erlotinib (Tarceva) osimertinib (Tagrisso) and/or afatinib dimaleate (Gilotrif)
- ER for fulvestarnt (Faslodex)
- F2
- F5
- FGFR2 for pegaptanib (Pemazyre)
- FGFR3 for erdafitinib (Balversa)
- FTL3 mutation assay for midostaurin (Rydapt), gilternib (Xospata) or sorafenib (Nexavar).
- G6PD for rasburicase (Elitek)
- GBA for velaglucerase alfa
- Genotype 1 chronic hepatits C for teleprevir (Incivik)
- HER2/neu for traztuzumab (Herceptin) and/or lapitinib (Tykerb)

- HLA-A for carbamazepine (Tegretol)
- HLA-B*1502 for persons of Asian ancestry prior to carbamazepine (Tegretol)
- HLA-B*5701 for Abacavir (Ziagen)
- HLA-B*5801 for allopurinol
- IFNL3, IFNL4 for peginterferon (Pegasys, Pegintron, Sylatron)
- K-RAS for cetuximab (Erbitux) and/or panitumumab (vectibix)
- KIT
- MGMT gene methylation assay for temozolomide (Temodar)
- MT-RNR1 for aminoglycosides
- NS3 Q80K for simeprevir (Olysio)
- NUDT15 for thiopurines
- PDGFRß for treatment with imatinib mesylate (Gleevec).
- PDL1 for pembrolizumab (Keytruda), durvalumab (Imfinzi).
- PD-L1 for treatment with durvalumab (Imfinzi); atezolizumab (Tecentriq), pembrolilzumab (Keytruda).
- PIK3CA for alpelisib (Piqray)
- ROS1
- RYR1 for inhaled anesthetics
- SLCO1B1 for Statins (class): simvastatin, pravastatin, atorvastatin, lovastatin, rosuvastatin, fluvastatin, pitavastatin
- TPMT gene mutation or phenotypic assay for 6-mercaptopurine or azathioprine therapy (See MP311 for additional information)
- UGT1A1 for irinotecan treatment
- VKORC1 for warfarin metabolism

Generally, pharmacogenetic testing such as mutation analysis or genotyping is considered to be medical necessary when:

- The member is a candidate for a targeted therapy as noted above; and
- The testing methodology used to investigate and identify the genetic mutation or biomarker has been proven to be clinically valid and analytically valid; and
- The test result has been proven to have clinical utility and will have a direct impact on the decision making and/or the member's clinical outcome; or
- When medications are being considered for use or are being administered that are known to have a gene-drug interaction that has been demonstrated to be clinically actionable as defined by the FDA.

If a single gene or allele test is ordered, but the laboratory tests that single gene or allele on a platform that looks for variants in other genes/alleles as well, the test is considered a single gene/allele test for coverage purposes and only the single gene test will be considered medically necessary.

A multi-gene panel is considered medically necessary if more than one single gene on that panel would be considered medically necessary for safe use of the medication in question or if multiple drugs are being considered (each fulfilling the criteria of actionable gene-drug interactions identified above) that have different relevant genes. A multi-gene panel is considered unproven and not medically necessary, therefore **NOT COVERED** if only a single gene on the panel is considered reasonable and necessary.

MEDICARE BUSINESS SEGMENT:

Pharmacogenomic testing for warfarin metabolism is eligible for coverage once per patient lifetime, corresponding to CYP2C9 and VKORC1 genotypes, respectively. Alleles CYP2C9 and VKORC1 for warfarin dosing are coverable per NCD 90.1 via coverage with evidence development. (http://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=333&ncdver=1&bc=BAAAgAAAAAAA&)

Pharmacogenomic testing of CYP2C19 for clopidogrel metabolism is eligible for coverage in individuals with acute coronary syndrome undergoing a percutaneous coronary intervention who are initiating or re-initiating clopidigrel therapy.

Pharmacogenomic testing of CYP2D6 is eligible for coverage in individuals in whom:

- Amitriptyline or nortriptyline is initiated for depressive disorder; or
- Tetrabenazine dosing greater than 50 mg/day
- Antidepressants for treatment of depression (including SSRI's) , Anti-psychotics for treatment of schizophrenia, atomoxetine, codeine, ondansetron, tropisetron, tamoxifen, tramadol, hydrocodone

MEDICAID BUSINESS SEGMENT:

Pharmacogenomic testing of CYP2C19 for clopidogrel metabolism is eligible for coverage as an Option 2 program exception once per patient lifetime when the request for this test is for an insured individual with documented moderate to high risk for an acute coronary event.

EXCLUSIONS:

Unless otherwise mandated, the Plan does **NOT** provide coverage for the use of the following pharmacogenetic testing because they 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 test on health outcomes when compared to established tests or technologies.

- CYP2D6 gene mutation for any of the following
  - Opioid analgesics
  - ~~Antidepressants for treatment of depression (including SSRI's)~~ **~~(exclusion not applicable to Medicare)~~**
  - ~~Anti-psychotics for treatment of schizophrenia~~
  - Tamoxifen resistance
- CYP1A2
- CYP3A4
- OPRM1 (μ-opioid receptor)
- OPRK1 (k-opioid receptor)
- DRD1 (dopamine receptor)
- DRD2 (dopamine receptor)
- DRD4 (dopamine receptor)
- DAT1 or SLC6A3 (dopamine transporter)
- DBH (dopamine beta-hydroxylase)
- TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism)
- IFNL3 (prediction of virological response to pegylated-interferon-alpha and ribavirin combination therapy)
- MTHFR (5, 10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis
- HTR2A (eg, citalopram metabolism) gene analysis, common variants
- HTR2C (eg, citalopram metabolism) gene analysis, common variants
- UGT2B15 (uridine diphosphate glycosyltransferase 2 family, member 15)
- COMT (catechol-O-methyl-transferase)
- ~~CYP2C19 for any of the following:~~
  - ~~Antidepressants~~
  - ~~Barbiturates~~
  - ~~Proton pump inhibitors~~
  - ~~Mephenytoin~~

Unless otherwise mandated, the Plan does NOT provide coverage for the use of any of the following pharmacogenetic testing panels because they are considered ~~experimental, investigational or~~ to be of unproven clinical value and not medically necessary:

- AIBioTech CardioloGene Genetic Panel
- AIBioTech Pain Management Panel
- AIBioTech PsychiaGene Genetic Panel
- AIBioTech Urologene Panel
- GeneSight ADHD
- GeneSight Assay for Refractory Depression **(not applicable to Medicare/Medicaid per MolDx L35633)**
- GeneSight Psychotropic **(may be considered for Medicaid via Program Exception)**
- GeneSight Analgesic
- Genecept Assay
- Genomind PGx
- SureGene Test for Antipsychotic and Antidepressant Response
- Millenium Pharmacogenetic Testing
- Proove Drug Metabolism Panel
- Proove Narcotic Risk Assay
- YouScript Panel
- PharmaRisk Basic
- PharmaRisk Psychiatric Panel
- Molecular Testing Labs Psychotropic Medication Panel
- Physicians Choice Laboratory Services Pharmacogenetic Testing
- NeuroIDGenetics
- CardioIDGenetics
- OnDose testing to allow area under the curve (AUC)-targeted 5-fluorouracil dosing
- OneOme RightMed Pharmacogenomic Test
- PGx Express CORE Anxiety & Depression (Genomind) **(may be considered for Medicaid via Program Exception)**
- Tempus nP
- IDgenetix

MP247 Nutritional Supplements – Revised – Update Coverage; Revise Medicare Coverage; Revise Exclusions

Medicare Business Segment:
please see LCD - Enteral Nutrition (L38955)
Article - Enteral Nutrition - Policy Article (A58833)

Oral Nutritional Products:
Oral nutritional supplementation is not covered under Medicare Part B.

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 insured individuals:
   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

Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of beneficiaries requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each case and supported by documentation of medical necessity. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary. (Refer to the LCD-related Policy Article **(A58833)** for policy specific documentation requirements.)

If a pump (B9002) is ordered, there must be documentation in the beneficiary's medical record to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not reasonable and necessary.

More than three nasogastric tubes (B4081, B4082, and B4083), or one gastrostomy/jejunostomy tube (B4087 or B4088) every three months is not reasonable and necessary.

In-line digestive enzyme cartridges (B4105) are reasonable and necessary for beneficiaries who:

A. meet the coverage criteria for enteral nutrition; AND
B. have a diagnosis of Exocrine Pancreatic Insufficiency (EPI)

More than two in-line digestive enzyme cartridges (B4105) per day will be denied as not reasonable and necessary

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~~

Inpatient Infant

Pasteurized donor human milk (PDHM) is covered for an infant who is younger than twelve months of age based on the infant's corrected gestational age, who is receiving care in an inpatient setting and has any of the following health conditions:

(1) An infant birth weight equal to or less than one thousand eight hundred grams.
(2) An infant gestational age equal to or less than thirty-four weeks.
(3) A high risk for development of necrotizing enterocolitis, bronchopulmonary dysplasia, sepsis or retinopathy of prematurity.
(4) A congenital or acquired gastrointestinal condition or other serious medical condition associated with long-term feeding or malabsorption complications.
(5) Congenital heart disease requiring surgery in the first year of life.
(6) Has had or will have an organ or bone marrow transplant, or has an immunologic deficiency.
(7) Renal disease requiring dialysis in the first year of life.
(8) Infant hypoglycemia or jaundice.
(9) Neonatal abstinence syndrome.
(10) Any other health condition for which the use of PDHM is medically necessary as determined by the Department.

Outpatient Infant – REQUIRES PRIOR AUTHORIZATION

PDHM is covered for an infant who is younger than twelve months of age based on the infant's corrected gestational age, who is receiving care in an outpatient setting and has any of the following health conditions:

(1) A congenital or acquired gastrointestinal condition or other serious medical condition associated with long-term feeding or malabsorption complications.
(2) Congenital heart disease requiring surgery in the first year of life.
(3) Has had or will have an organ or bone marrow transplant or has an immunologic deficiency.
(4) A history of sepsis.
(5) Renal disease requiring dialysis in the first year of life.
(6) Any other health condition for which the use of PDHM is medically necessary as determined by the Department.

- 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.)

ALL BUSINESS SEGMENTS: (with exceptions as noted)

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 nutrition for temporary impairments is **NOT COVERED.**

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

Orally administered enteral nutrition products, related supplies and equipment is **NOT COVERED.**

Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system will be denied as **NOT COVERED. (Exclusion for B4100 NOT Applicable to Medicaid Business Segment)**

Enteral formula additives are **NOT SEPERATELY REIMBURSED.**

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. (Not applicable to Medicare lob)**
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.

MP265 Proteomic Serum Analysis – Revised – Reverse CXBladder coverage for Medicare

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.

MolDx 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.

~~In compliance with Novitas LCD A58529 Response to Comments: Biomarkers for Oncology, **Cxbladder™ Detect, Cxbladder™ Monitor** will be covered when meeting the reasonable and necessary guidelines as outlined in Title XVIII of the Social Security Act, Section 1862(a)(1)(A).~~

EXCLUSIONS: All Business Segments Except as Annotated

PA Dept. of Human Services has determined OVA1 assay may be considered on a per-case basis through the Program Exception process

Unless otherwise mandated (eg, Medicare), 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 (eg, Medicare), 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.

~~Unless coverage is mandated, the~~ 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.

MP328 Genetic Susceptibility Cancer Panels – Revised – Revise Criteria

INDICATIONS: <u>REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE</u>

For members presenting with a personal or family history of cancer suggestive of hereditary breast and ovarian cancer syndrome please refer to **MP097 Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer**

- HBOC related cancers include: breast, ovary, pancreas, and prostate

For members presenting with a personal or family history of cancer suggestive of Lynch syndrome (LS), Familial Adenomatous Polyposis (FAP), MUTYH-associated polyposis (MAP), and rare polyposis syndrome such as Peutz-Jeghers or Juvenile Polyposis please refer to **MP098 Genetic Testing Related to Colorectal Cancer.**

- LS-related cancers include: brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal, small intestine, prostate, or ureter cancers, sebaceous adenomas, and sebaceous carcinomas.
- FAP, MAP, and rare polyposis syndromes are described in the above policy.

Genetic evaluation using a multi-gene cancer panel is considered medically necessary in members who have:

1. A personal or family history that is consistent with Hereditary Breast & Ovarian Cancer Syndrome (HBOC) *or* Lynch syndrome (LS), **AND**
   a) prior testing was limited (e.g. BRCA1 and BRCA2 sequencing only), or included high-penetrance genes only (e.g. *BRCA1, BRCA2, MLH1, MSH2, MSH6, PMS2, EPCAM, PTEN, STK11, TP53,*) and the result was negative or indeterminate; **AND**
   b) update testing is available with genes that have medical management recommendations per NCCN.

OR

2. A personal history of *any* solid tumor type, where more than one gene may be associated with an inherited cancer syndrome **AND** may be suggestive of more than one hereditary cancer syndromes where limited or targeted testing may miss actionable variant(s) (eg. Cowden Syndrome, Lynch syndrome, Hereditary Leukemia and Hematologic Malignancies Syndromes, Li-Fraumeni Syndrome, Von Hippel-Lindau disease, Multiple endocrine neoplasias, etc.) **OR**

3. When **ALL of the following** criteria are met:
   - The suspected hereditary cancer syndrome(s) can be diagnosed by one or more of the genes included in the requested hereditary cancer panel; **and**
   - The results of testing will directly impact the member's clinical management options; **and**
   - The member's personal and family history has been evaluated by a non-lab employed genetic counselor or a non-lab employed adequately trained health care professional, and the pedigree analysis is suggestive of an inherited susceptibility including **at least one of the following**:
     - A personal history of, or at least one first-degree blood relative with a history of, at least two different primary solid tumors at any age, or
     - A personal history of a solid tumor with at least one somatic finding reported at an allele frequency suggestive of potential germline etiology, or
     - A personal history of an HBOC- or LS related cancer, or at least one first- or second-degree blood relative with a history of, an HBOC- or LS related cancer at any age, or
     - A personal history of a malignancy meeting NCCN criteria for evaluation of inherited cancer risk; or
     - ~~A personal history of an LS-related cancer and at least one first- or second-degree blood relative with an LS-related cancer at any age~~.
     - At least three people on the same side of the family with the same type of malignancy.
       - The member does not need to be affected, but a first-degree relative must have a combination of first, second, or third-degree blood relatives, on the same side of the family, diagnosed with any solid tumor or a hematologic malignancy of the same origin (e.g. myeloid vs lymphoid).

MP368 Carotid Sinus Baroreflex Device – NEW

DESCRIPTION:
Baroreceptors are pressure sensors contained within the walls of the carotid arteries. They are part of the autonomic nervous system that regulates basic physiologic functions such as heart rate and blood pressure. When these receptors are stretched, which occurs with increases in blood pressure, the baroreflex is activated. Activation of the baroreflex signals the brain, which responds by inhibiting sympathetic nervous system output and increasing parasympathetic nervous system output. The effect of

this activation is to reduce heart rate and blood pressure, thereby helping to maintain homeostasis of the circulatory system.

The use of baroreflex stimulation devices (also known as baroreflex activation therapy [BAT]) is a potential alternative treatment for resistant hypertension and heart failure.

EXCLUSIONS:
The Plan does **NOT** provide coverage for Carotid Sinus Baroreflex Device because they are considered **unproven** and therefore **not medically necessary**. Although the devices are FDA approved, 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.

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.

MP034 Foot Orthotics
MP066 ESWT
MP078 Sexual Dysfunction Therapies
MP090 Inj. Bulking Agents/Incontinence
MP094 Unilateral Pallidotomy
MP113 Electrical Stim Wound Healing
MP172 MicroVas Vascular Treatment System
MP196 Convection-Enhanced Drug Delivery
MP249 Bioimpedance Spectroscopy
MP310 Vertical Expandable Titanium Rib
MP320 Absorbable Hydrogel Spacer
MP326 Biomarker Testing for Rheumatoid Arthritis
MP334 Genetic Testing for Macular Degeneration
MP340 Wide Area Transepithelial Sampling (WATS)
MP353 Laser Interstitial Thermal Therapy