"What's New" Medical Policy Updates July 2024

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, 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.

MP004 Biofeedback – Revised – Added Exclusion

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

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

Surface electrode electromyography (sEMG) Biofeedback is considered to be of **Unproven** value and **therefore NOT COVERED.** There is insufficient evidence in the published peer-reviewed medical literature to support the use of home (unattended) sEMG/Biofeedback for any indication**.**

Neurofeedback is considered to be of **Unproven** value and therefore **NOT COVERED**. There is insufficient evidence in the published peer-reviewed medical literature to support the use of neurofeedback for any indication.

MP045 Chest Percussion Vest – Revised – Added Exclusion

EXCLUSION:
It is not medical necessary for an insured individual to use both a high frequency chest wall percussion device and a mechanical in-exsufflation device (E0482).

Requests for coverage for insured individuals with the approved diagnoses and not meeting the above criteria, or requests for insured individuals with ANY other diagnosis must be authorized by a Plan Medical Director or designee.

Combination oscillation and lung expansion (OLE) devices for the treatment of respiratory conditions (e.g., the Volara System, BiWaze Clear System, and MetaNeb4 System) **(E1399)** as an alternative to conventional chest physical therapy to promote the clearance of respiratory secretions are considered to be of unproven value and not medically necessary, therefore **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to draw conclusions regarding improvements in health outcomes of these devices compared to established alternatives.

MP136 Alternative Medicine Therapies – Revised – Added 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	Hydrazine sulfate
Aromatherapy	Hydrogen peroxide therapy
Ayurveda	Hydrotherapy* (eg, spa therapy, water cure, etc.)
Art therapy *	Livingston-Wheeler therapy
Apitherapy	Magnet therapy
Bioidentical hormone therapy	Mistletoe extract
Biomagnetic therapy	Moxibustion
Chinese herbal medicine	Music therapy*
Colonic irrigation	Polarity therapy
Cupping	Purging
Dance/Movement therapy	Qigong
Di Bella Cancer Therapy	Reflexology
Gemstone therapy	Reiki
Gerson therapy	Revici's guided chemotherapy
Greek cancer cure	Rolfing
Guided imagery	Shark cartilage products
Herbal medicine	Therapeutic touch
Hippotherapy	Yoga
Homeopathy	Exercise With Oxygen Therapy (EWOT)
Hoxsey method	Transcendental meditation
Humor therapy	Electrodermal stress analysis
Sauna	Primal therapy
Psychodrama	Pilates
Polarity therapy	Ozone therapy
Whole body vibration therapy	Insulin potentiation therapy
Inversion therapy	Intravenous micronutrient therapy (Myers' Cocktail)
Intravenous vitamin C infusion	Bee sting therapy
Body wraps	Placentophagy
Wilderness Therapy	Emotional Freedom Technique (aka, EFT, Tapping)
Brainspotting	Kambo Cleanse Therapy

MP209 Medical Error "Never Events", Hospital Acquired Conditions, and Hospital Readmission – Revised – Revise Process Information

PROCESS:
Geisinger Health Plan (the Plan):

- Requires the acute care inpatient facility to be responsible for reporting Hospital Acquired Conditions (HACs) as defined by CMS to Geisinger Health Plan.
- Will monitor Serious Reportable Events (SREs)/HACs through case management, member complaints, claims review, and other channels.
- ~~The report will include the following information:~~
    - ~~Member name~~
    - ~~Medical record number~~
    - ~~Date of birth~~
    - ~~Date of event~~
    - ~~Inpatient or outpatient status at time of event~~
    - ~~Discharge date or date of expiration~~
    - ~~Provider name~~
    - ~~Description of event~~

- Geisinger Health Plan follows CMS guidelines for reporting POA indicators. Applicable facilities are required to submit POA indicators for all product lines.
- The Present on Admission (POA) Indicator requirement applies to all inpatient acute care hospitals with the following exceptions:
    - Critical Access Hospitals (CAHs)
    - Long-term Care Hospitals (LTCHs)
    - Cancer Hospitals
    - Children's Inpatient Facilities
    - Rural Health Clinics
    - Federally Qualified Health Centers
    - Religious Non-Medical Health Care Institutions
    - Inpatient Psychiatric Hospitals
    - Inpatient Rehabilitation Facilities
- ~~All cases will have a quality investigation according to Quality Improvement Policy 08, Medical Care/Public Concern and Never Event Policy~~
- Reserves the right to partially or totally withhold payment for all provider costs associated with the "never event" at its discretion, based on the severity of the incident.
- Review the SRE/HAC list at least annually and update accordingly
- ~~All cases will be referred to the Medical Error/Payment Determination Committee~~. The Payment Review and Determination shall be made consistent with the intent of this Policy and with recognition of the following variables:
    - The timing of the occurrence of the SRE/HAC, within the patient's episode of care;
    - ~~o~~ The specific roles as well as clinical and procedural requirements of the providers involved in the patient's episode of care (e.g. surgeons, anesthesiologists, hospital-based physicians and nursing staff, etc.);
    - ~~Patient behavior.~~

~~It may result in the following actions:~~

- ~~Full Denial of Payment~~

~~Partial Denial of Payment - Based on DRG assignment reflecting the Present on Admission~~

MP219 Implantable Percutaneous Electrical Nerve Stimulation (PENS) and Neuromodulation Therapy (PTN) – Revised – Added Language; Added Exclusions

DESCRIPTION:

Percutaneous Peripheral Nerve Stimulation

PENS is performed with needle electrodes to stimulate peripheral sensory nerves in the soft tissue. Percutaneous neuromodulation therapy (PNT) is a variant form of Percutaneous Electrical Nerve Stimulation (PENS) in which up to 10 fine filament electrodes are temporarily placed at specific anatomical landmarks in the back. Treatment regimens consist of 30-minute sessions, once or twice a week for approximately eight to ten sessions. This modality is thought to offer symptomatic relief and management of chronic or intractable pain.

Implantable Peripheral Nerve Stimulation

Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation therapy in which electrodes are surgically placed next to a selected peripheral nerve considered to be the source of chronic pain. The electrode delivers electrical energy to the affected nerve. This electrical current is thought to disrupt the normal transmission of pain signals resulting in reduced levels of pain.

Restorative Neurostimulation

Restorative neurostimulation is a minimally invasive method of innervating the multifidus muscle of the lower back to override the cycle of lumbar multifidus muscle degeneration. It is intended to be used as a

rehabilitative therapy for individuals with impaired neuromuscular control associated with mechanical chronic low back pain.

EXCLUSIONS:
The Plan does **NOT** provide coverage for Implantable Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy (PTN) for any indication because it is considered **~~experimental, investigational or~~ unproven** and not medically necessary, and therefore **NOT COVERED.** 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 Remote Electrical Neuromodulation (e.g. Nerivo) for any indication because it is considered to be **Unproven** and not medically necessary and therefore **NOT COVERED**. 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 restorative neurostimulation (e.g., ReActiv8, StimRouter PNS System, StimQ, Nalu) for any indication including but not limited to chronic low back pain is considered **Unproven** and not medically necessary and therefore **NOT COVERED**. 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 – Revise Coverage

Commercial Business Segments: (Coverage may vary by individual TPA)

Oral Nutritional Products:

Oral nutritional products are not covered unless mandated by law (**see Exclusions)**

Enteral nutrition (including administration, supplies and formula) 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

Amino acid-based Elemental formula may be considered to be medically necessary in members age 5 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

Digestive enzyme cartridges (e.g. Relizorb) (B4105) used in conjunction with enteral nutrition therapy is considered to be medically necessary only when the following criteria are met:

- Member is aged 2 or above for the treatment of pancreatic insufficiency due to cystic fibrosis; and
- criteria for Enteral Nutrition has been met; and
- documented failure of pancreatic enzyme replacement therapy OR documented intolerance or hypersensitivity to all other digestive enzyme aids; and
- Failure to achieve or maintain target body mass index (at or above the 50th percentile)

Note: Other etiologies resulting in exocrine pancreatic insufficiency will be considered on a per-case basis

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

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

Digestive enzyme cartridges (e.g. Relizorb) (B4105)
NOTE: Digestive enzyme cartridges (e.g. Relizorb) used in conjunction with enteral nutrition therapy may be considered on a per-case basis through the Program Exception process for Medicaid Business segment members ages 2 years and older with exocrine pancreatic insufficiency who are partially or completely unable to hydrolyze fats in enteral formula.

MP271 Non-Invasive Testing for Fetal Aneuploidy – Revised – Revised Description and Indications; Added Exclusions

DESCRIPTION: Non-invasive prenatal testing (NIPT) describes a family of tests that rely on the analysis of cell-free DNA (cfDNA) fragments, derived from the placenta, in the plasma of a pregnant person. This technology is designed to screen fetuses for common autosomal trisomies (trisomy 21, 18, and 13) and is not a diagnostic test. The sensitivity and specificity has improved over time in the context of fetal aneuploidy detection. There are two methods to testing: chromosome counting and SNP-based testing. SNP-based testing has a higher accuracy and lower sample fail rate as well as the ability to detect triploidy. Some NIPT laboratories also test for sex chromosome abnormalities (Monosomy X [Turner syndrome], XXY [Klinefelter syndrome], XXX, XYY, and various more complex karyotypes).

NIPT is not validated in multiples (eg: greater than twin pregnancy) and not recommended for screening.

Emerging technology includes expanded aneuploidy screening involving the other autosomes exists but the utility remains unclear in low risk pregnancies ~~Circulating cell-free DNA purified from maternal blood plasma is analyzed to detect aneuploidies at chromosome 21 (Down syndrome), chromosome 18 (Edwards syndrome), and chromosome 13 (Patau syndrome).~~ NIPT and cfDNA technology has been applied to the screening of specific autosomal dominant and autosomal recessive disorders with serious health implications. These are monogenic conditions referring to a group of human conditions caused by inherited or de novo pathogenic variants in a single gene. Although individually rare, in aggregate, they are common and many have chronic implications for patients with some being life-limiting.

The American College of Obstetricians and Gynecologists (ACOG)'s clinical recommendations for Screening for Fetal Chromosomal Abnormalities (Practice Bulletin #226) provides an evidence-based analysis of the available medical literature that resulted in the recommendation that all patients should be offered both screening and diagnostic testing options, regardless of maternal age and risk of chromosomal abnormality. Chromosomal abnormalities occur in approximately 1 in 150 live births and the incidence of fetal chromosomal abnormalities increases as a woman ages but can affect patients at any age and is not related to race or ethnicity.

There are several different tests available for identifying these aneuploidies. These tests include, but are not limited to

- QNatal Test (Quest Laboratory)
- MaterniT21™ Plus Tests ~~(Sequenom Center for Molecular Medicine [Grand Rapids, MI]~~ LabCorp), ~~the~~
- Verifi™ Prenatal Test ~~(Verinata HealthIllumia Inc. [Redwood City, CA]);~~
- Harmony Prenatal Test ~~(Aria Diagnostics, San Jose, California~~ Roche Diagnostics); ~~and the~~
- Panorama™ or Vasistera™ Prenatal Test [(Natera ~~San Carlos, CA)];~~
- Prequel Prenatal Screen (Myriad Genetics).

There are several different cffDNA tests available for identifying RhD status in a fetus, including but not limited to :

- Panorama™ Prenatal test with RhD (Natera)
- Billion to One RhD

~~MaterniT21™ Plus tests (Sequenom Center for Molecular Medicine [Grand Rapids, MI]), the Verifi™ Prenatal Test (Verinata Health Inc. [Redwood City, CA]); Harmony Prenatal Test (Aria Diagnostics, San Jose, California) and the Panorama™ Prenatal Test [Natera San Carlos, CA].~~

INDICATIONS:

Non-Invasive Testing for Fetal Aneuploidy NIPT

NIPT may be considered to be medically necessary when all of the following criteria are met:

1. ~~1.~~ The testing is ordered by an obstetric, fertility, or family medicine care provider; ~~and a Maternal Fetal Medicine specialist, Obstetrician or other obstetric care provider; and~~
2. The member is currently pregnant with a singleton or twin pregnancy; and
3. The member is at least 9 weeks 0 days gestational age by LMP or ultrasound; and
4. The member desires information about the chance for a pregnancy affected by a chromosomal aneuploidy

~~One or more of the following conditions (defined by The American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics and The Society for Maternal-Fetal Medicine (SMFM) Publications Committee) are met:~~

- ~~Cell-free fetal DNA-based prenatal screening for fetal aneuploidy (trisomy 13, 18, and 21) in members with a current singleton or twin pregnancy); or~~
- ~~Cell-free fetal DNA-based prenatal screening in members with a current singleton pregnancies at increased risk of a sex (X)-linked condition or congenital adrenal hyperplasia.; or~~

- ~~Fetal ultrasonographic findings indicating an increased risk of aneuploidy; or~~
- ~~History of a prior pregnancy with a trisomy; or~~
- ~~Positive test result for aneuploidy, including first or second trimester, sequential, or integrated screen, or a quadruple screen; or~~
- ~~Parental balanced Robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21.~~

Non-Invasive Testing for Fetal Triploidy

1. Repeat NIPT may be considered medically necessary when a current pregnancy demonstrates signs of a molar or partial molar pregnancy, but ultrasound alone is insufficient for diagnosis; or
2. Limited NIPT was completed during the member's current pregnancy but did not include analysis for triploidy

Non-Invasive fetal antigen ~~RhD~~ genotyping (example: RhD Screening)

Screening for fetal RhD status using cell-free fetal DNA ~~(cfDNA) using the SensiGene Fetal RhD genotyping testing~~ is considered to be **medically necessary.**

Non-Invasive Prenatal Testing for single gene, autosomal dominant disorders (example: Natera Vistara)

Vistara testing is considered medically necessary in the following scenarios:

1. The member's pregnancy is considered high risk due to the father or sperm donor of the pregnancy being classified as advanced paternal age (45y or older); or
2. The member's pregnancy is affected by an ultrasound-proven anomaly; or
   There is family history of one of the disorders evaluated on the screening test and invasive testing has been declined or is not available that the current gestational age.

LIMITATION:

Noninvasive prenatal testing (NIPT~~NPIT~~) using cell free fetal DNA in maternal plasma for trisomy 13 and/or 18 is considered to be experimental, investigational or unproven, unless performed with trisomy 21 screening analysis.

EXCLUSIONS:

The use of Non-Invasive Testing for Fetal Aneuploidy for any indication not conforming the criteria listed in this policy is considered to be **experimental, investigational or unproven**, and therefore **NOT COVERED**.

Noninvasive prenatal testing using cffDNA for expanded aneuploidy screening in a low risk pregnancy is considered to be experimental, investigational or unproven, and therefore **NOT COVERED**

The use of cell-free DNA (cfDNA) for screening and diagnosis of single-gene disorders (e.g., Billion To One UNITY Screen) is an evolving technology, and its application at this time is limited. At this time, it is considered to be **experimental, investigational or unproven**, and therefore **NOT COVERED**.

The use of cell-free DNA (cfDNA) for screening and diagnosis of microdeletions (e.g., DiGeorge syndrome, Prader-Willi syndrome, Angelman syndrome, 1p36 deletion syndrome, Cri-du-chat syndrome, Wolf-Hirschhorn, Miller-Dieker), or aneupoidies other than trisomy 13, 18, or 21 is considered to be **experimental, investigational or unproven**, and therefore **NOT COVERED**.

The use of Non-Invasive Testing for Fetal Aneuploidy to determine the sex of fetus is not medically necessary, and therefore is **NOT COVERED** in the absence of increased risk of Turner Syndrome or congenital adrenal hyperplasia.

Nucleic acid sequencing-based testing of maternal plasma for microdeletions and single gene disorders is considered to be experimental, investigational or unproven, and therefore **NOT COVERED.**

MP307 Gender Dysphoria and Gender Confirmation Treatment – Revised – Add Exclusion

EXCLUSIONS: The following procedures are considered to be cosmetic and not medically necessary to complete gender transition:

- Blepharoplasty (unless criteria per MP10 are met apart from gender reassignment)
- Rhinoplasty (unless criteria per MP204 are met apart from gender reassignment)
- Collagen injections
- Electrolysis (other than noted above)
- Rhytidectomy (i.e. face lift)
- Facial implants, injections, or bone reduction (may be considered on a per-case basis with appropriate clinical documentation)
- Hair removal (except as noted in the MtF indication tables)
- Hair transplantation
- Medication to promote hair growth
- Lip reduction or enhancement
- Liposuction
- Removal of redundant skin (unless criteria per MP56 are met apart from gender reassignment)
- Silicone injections
- Body sculpting (e.g., masculinization or feminization of face, torso, body contouring, gluteal augmentation, etc.)
- Skin resurfacing (e.g., dermabrasion, microneedling, chemical peels, laser) in the absence of malignant or pre-malignant lesions

MP314 Molecular Testing - General Guidelines – Revised – Added Description Language

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. The clinical utility may be in diagnosing or predicting susceptibility of inherited conditions and disorders and in selecting appropriate treatment or monitoring response to treatment. Testing can be limited to single gene variants or across multiple genes. Next generation sequencing, chromosomal microarray, exome and genome testing has led to the ability to examine many genes simultaneously. When appropriate, panel tests can screen for numerous variants within a single gene or multiple genes more efficiently in the diagnostic work-up of genetic disorders. One potential challenge is the identification of genetic variants of unknown clinical significance and/or variants for which the clinical management is uncertain.

MP323 Molecular Profiling of Malignant Tumors to Identify Targeted Therapies – Revised – Added Coverage Language

FoundationOne Liquid CDx: (Commercial and Medicare Business Segments) 0239U

FoundationOne Liquid CDx circulating tumor cell free DNA (cfDNA) molecular profiling testing is considered to be medically necessary at diagnosis or progression for the following indications when the criteria are met:

- Member has a diagnosis of solid tumor cancer; and
- Treatment is being considered with a medication for which there is an FDA-approved companion diagnostic assay; and

- FDA label for the drug and indication being considered states companion diagnostic testing is necessary for patient selection

Note: FDA-approved companion diagnostic indications can be found here, https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools

1. ~~FoundationOne Liquid CDx is considered to be medically necessary to identify single gene alterations, rearrangements and copy-number alterations including all NTRK fusions, in all solid tumors; or.~~

2. ~~A diagnosis of non-small cell lung cancer is suspected but the member's physical condition poses unacceptable risk for invasive biopsy;~~ **~~or~~**
   ~~A diagnosis of non-small cell lung cancer has been confirmed on pathology, but insufficient tumor sample is available for molecular testing;~~
   ~~and~~

   ~~The treating physician will use the results to guide therapy~~
   ~~or~~
3. ~~FoundationOne Liquid CDx is considered to be medically necessary as a companion diagnostic test for the PARP inhibitor rucaparib (Rubraca) in metastatic castration-resistant prostate cancer patients with BRCA mutations, and three EGFR inhibitors for the first-line treatment of non-small cell lung cancer (NSCLC) in patients with certain EGFR mutations -- gefitinib (Iressa), osimertinib (Tagrisso), and erlotinib (Tarceva).~~

FoundationOne Heme: (Commercial and Medicare Business Segments) 81450, 81455

- The member has a diagnosis of AML, MDS or MPN. AML, MDS and MPN are herein classified as refractory and/or metastatic cancers and fulfil the NCD 90.2 criteria.
- The test has satisfactorily completed a TA by MolDX® for the stated indications of the test.
- The assay performed includes at least the minimum genes and positions indicated for its intended use, as described in an associated coverage Article or found in the TA forms.
- For members that do not have a diagnosis of a myeloid malignancy, where one is suspected, the member must have an undefined cytopenia for greater than 4 months, other possible causes have been reasonably excluded.
- Testing is performed on bone marrow biopsies, bone marrow aspirates, bone marrow clots, peripheral blood samples, or extramedullary sites suspected of harboring a myeloid malignancy.

Guardant360 and Guardant360CDx: (Commercial) 0242U, 0334U

Molecular profiling to identify targeted therapies utilizing Guardant360 CDx will be considered medically necessary for any the following indications when criteria are met:

1. Guardant360 and Guardant360CDx is considered medically necessary to provide information biomarkers in all solid tumors
   - The member is a candidate for further treatment with a drug that is either FDA-approved for that cancer, or has an NCCN 1 or NCCN 2A recommendation for that cancer, or
   - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360 or Guardant360 CDx assay

For the MEDICARE BUSINESS SEGMENT:

Guardant360 and Guardant360 CDx is covered when the member:

- has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system, **and**
- is untreated for the primary cancer being tested, or is not responding to treatment, **and**
- has decided to seek further cancer treatment with the following conditions:
    - The member is a candidate for further treatment with a drug that is either FDA-approved for that cancer, or has an NCCN 1 or NCCN 2A recommendation for that cancer, **and**
    - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360 CDx assay

Guardant360 Response (Commercial and Medicare) 0422U
Guardant360 Response is considered medically necessary for members who have metastatic or inoperable solid tumors who are on an immune checkpoint inhibitor therapy to monitor response to immunotherapy .

OncoExTra (Commercial and Medicare) 0329U

OncoExTra is considered medically necessary for any the following indications when criteria are met:

- The member is diagnosed with an unresectable or metastatic solid tumor(s); and
- The test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy;
  and
- The member has progressed following prior treatment

Define MBC Metastatic Breast Cancer Panel (Commercial and Medicare) 0428U
Define MBC Metastatic Breast Cancer Panel is considered medically necessary for members who have metastatic breast cancer and for whom tissue-based, comprehensive genomic profiling is infeasible.

oncoRevealTM DX Lung and Colon Cancer Assay (Commercial and Medicare) 0448U
oncoRevealTM DX Lung and Colon Cancer Assay is considered medically necessary for members who require EGFR & KRAS therapy selection in non-small cell lung cancer (NSCLC) and colorectal cancer (CRC)

Oncotype MAP™ Pan-Cancer Tissue Test (Commercial and Medicare) 0244U
Oncotype MAP™ Pan-Cancer Tissue Test is considered medically necessary for members who have:

- Recurrent cancer
- Relapsed cancer
- Refractory cancer
- Metastatic cancer
- Advanced cancer (stages III or IV)

AND has not been previously tested by the same test for the same genetic content,
AND is seeking further treatment

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
MP074 Interactive Metronome Training
MP084 Stereotactic Radiosurgery
MP089 Evaluation of Breast Ductal Lavage
MP110 Uterine Artery Embolization

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)
MP249 Bioimpedance Spectroscopy
MP256 Transoral Incisionless Fundoplication
MP275 Speech Generating Devices
MP344 Sublingual Immunotherapy
MP345 Peroral Endoscopic Myotomy (POEM)
MP358 Home Accessibility Durable Medical Equipment
MP359 Medical Daycare
MP372 Electrodermal and Surface Electromyographic Seizure Detection Devices