“What’s New” Medical Policy Updates June 2023

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of May that will become **effective July 15, 2023** (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.

MP054 Prophylactic Mastectomy – (Revised) – Revise Criteria and Exclusions

Tryer-Cuzick model: The Tyrer-Cuzick risk model or IBIS risk tool assesses a women's 10 year and lifetime risk of developing breast cancer.
Breast Cancer Risk Calculator: The tool uses a woman’s personal medical and reproductive history and the history of breast cancer among her first-degree relatives (mother, sisters, daughters) to estimate absolute breast cancer risk or probability of developing invasive breast cancer in a defined age interval.

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

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

High Risk Criteria - the member must meet **at least one** of these criteria:

- ~~Two or more first-degree relatives with breast cancer~~
- ~~One first-degree relative and two or more second-degree or third-degree relatives with breast cancer~~
- ~~One first-degree relative with breast cancer before the age of 45 years and one other relative with breast cancer~~
- ~~One first-degree relative with breast cancer and one or more relatives with ovarian cancer~~
- ~~Two second - degree or third-degree relatives with breast cancer and one or more with ovarian cancer~~
- ~~One second-degree or third-degree relative with breast cancer and two or more with ovarian cancer~~
- ~~Three or more second-degree or third-degree relatives with breast cancer~~
- ~~One first-degree relative with bilateral breast cancer~~
- ~~Presence of a BRCA1 or BRCA2 mutation in the member consistent with a BRCA1 or BRCA2 mutation in a family member with breast or ovarian cancer.~~
- ~~Presence of a TP53 mutation (Li-Fraumeni syndrome), or PTEN mutation (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), in the member or a first degree relative~~
- ~~For members with biopsies showing lobular carcinoma in situ (LCIS) or who are at high risk for breast cancer related to having a previous carcinoma in one breast.~~
- ~~History of exposure or treatment with thoracic radiation before the age of 30~~
- ~~Presence of PALB2, CDH1 or STK11 mutation in conjunction with family history of breast cancer. (Note: there are insufficient data to support risk-reducing mastectomy based on the presence of PALB2, CDH1 or STK11 mutation alone)~~
- Members with a strong family history of breast cancer such as:
    - A family history of breast cancer in multiple first-degree relatives and/or multiple successive generations of family members with breast and/or ovarian cancer (family cancer syndrome); **and**

- The member's risk of breast cancer is elevated based on a validated assessment tool such as the Breast Cancer Risk Calculator, Gail Model, or Tyrer-Cuzick Risk Calculator; **and**
- The member has undergone counseling from an appropriate provider such as gynecologist, breast surgeon or genetic counselor to quantitate their risk;

or

- The member has tested positive for BRCA1, BRCA2, TP53, PTEN or PALB2 gene mutations; **or**
- The member has a high-risk histology: Atypical ductal or lobular hyperplasia, or lobular carcinoma in situ confirmed on biopsy; **or**
- Members with such extensive mammographic abnormalities e.g., calcifications), cystic/dense breast tissue) that adequate biopsy is impossible; **or**
- Members with a personal history of breast cancer making it more likely to develop a new cancer in the opposite breast; **or**
- Members who received radiation therapy to the thoracic region before the age of 30. (e.g. radiation to treat Hodgkin's disease).

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

EXCLUSIONS:
Prophylactic mastectomy for cancer risk reduction in members not meeting the criteria outlined in this policy is considered experimental, investigational, or unproven, and therefore **NOT COVERED**.

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

~~Prophylactic mastectomy is considered **experimental, investigational, and unproven** for members with nonproliferative fibrocystic changes (benign breast changes or fibrocystic changes) or proliferative disease without atypia~~.

MP057 Prophylactic Oophorectomy – (Revised) – Revise Criteria

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

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

7. Members with a known familial cancer syndrome associated with increased risk of ovarian cancer (e.g., hereditary nonpolyposis colorectal cancer [HNPCC], Lynch syndrome)

All members considering a prophylactic oophorectomy must undergo counseling regarding cancer risks from a genetic counselor.

MP060 Lung Volume Reduction Surgery – (Revised) – Remove Exclusion

ENDOBRONCHIAL VALVE LUNG VOLUME REDUCTION Please see MP370

EXCLUSIONS:
The Plan does not cover Laser bullectomy for emphysema or bronchoscopic lung volume reduction procedures (e.g., ~~bronchial valve placement~~, biologic lung volume reduction, bronchopulmonary fenestration) because they are considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this procedure on health outcomes when compared to established tests or technologies.

MP071 Continuous Subcutaneous Glucose Monitor CSGM – (Revised) – Revise Criteria

FOR MEDICARE BUSINESS SEGMENT:

Per CMS, Therapeutic (non-adjunctive) ~~or non-therapeutic (adjunctive) CGM~~ may be covered ~~by Medicare~~ when **all of the following** criteria are met:

- The member has diabetes mellitus; **and**,
- The member is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; **and**,
- The member's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results **and**
- The member is insulin-treated; **or**,
- The member has a history of problematic hypoglycemia with documentation of at least one of the following:
    - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; **or**,
    - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.
- The member is engaged in routine periodic visits with their treating provider for ongoing assessment and management of their diabetes.

MP168 Non-invasive Testing for Organ transplant Rejection – (Revised) – Add Exclusion

The Plan does **NOT** provide coverage for the use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after lung transplantation, including but not limited to the detection of acute transplant rejection or transplant graft dysfunction 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.

MP199 Corneal Pachymetry – (Revised) – Add Limitation Clarification

LIMITATIONS:
Corneal pachymetry testing for the evaluation of glaucoma is considered medically necessary once per lifetime.
Note: The lifetime limit ONLY applies for measurements done to assess corneal thickness, in conjunction with a glaucoma diagnosis. The limit does not apply in cases where the assessment of corneal thickness is required after ocular trauma (surgical or accidental) has been sustained, including the management of bullous keratopathy resulting from surgical or accidental trauma, or in Fuch's dystrophy.

MP232 Autism Spectrum Disorder Evaluation and Medical Management – (Revised) – Update Criteria

Applied Behavior Analysis ~~(covered only for member eligible for state mandated services)~~

- Criteria for coverage will be ~~managed by the Plan's behavioral health vendor and~~ in accordance with the OMHSAS Bulletin Medical Necessity Guideline for ABA using BSC-ASD & TSS Services for Children & Adolescents with ASD issued Jan 13th 2017.

~~Psychiatric or Psychological Services~~

- ~~Criteria for coverage will be managed by the Plan's behavioral health vendor.~~

MP280 Whole Exome Sequencing – (Revised) – Revise Indications and Exclusions

INDICATIONS: REQUIRES PRIOR AUTHORIZATION by a Plan Medical Director or Designee
Whole exome sequencing will be considered for coverage ~~when used for the evaluation of exomic sequence changes~~ when **all of** the following criteria are met:

1. Test is ordered by one of the following provider types:
   - Medical Geneticist
   - Genetics Nurse Practitioner
   - Licensed and/or Certified Genetic Counselor with a ~~care~~ provider involved in patient evaluation or follow up of results (examples: neurologist, neonatologist, psychiatrist)
   - Neurologist in collaboration with a medical geneticist or certified genetic counselor
   - Developmental Pediatrician ~~in collaboration with a medical geneticist or certified genetic counselor~~
   - Psychiatrist in collaboration with a medical geneticist or certified genetic counselor

   and

2. The test would confirm or establish a diagnosis that may lead to changes in medical management in any of the following ways:
   Guide specific clinical management, decision-making, preventive surveillance, or outcomes specified by the ordering provider
   Apply specific treatments, or withhold of contraindicated treatments,
   Surveillance for later-onset comorbidities,
   Initiation of palliative care or withdrawal of care versus continued treatment,

   and
3. The member or parents/legal guardians have been appropriately counseled about the testing's benefits and limitations by a qualified professional who is not employed by or contracted with a commercial genetic testing laboratory.

   and

4. The member is:
    a. A **child** (defined as under the age of 21) who exhibits at least one of the following:
        - Autism spectrum disorder;
        - non-syndromic developmental delay, cerebral palsy, loss of developmental milestones, ~~or~~ intellectual disability, or a cognitive disability
        - One or more structural congenital anomalies or malformation(s),
        - Two or more dysmorphic features not specific to a well delineated genetic syndrome
        - Suspected Mendelian condition in which multiple genes could potentially account for the phenotype
        - Complex epilepsy, ~~including drug resistant epilepsy~~ or epileptic encephalopathy

Or

    b. An **adult** who exhibits at least ~~has been diagnosed with~~ one or more of the following:
        - Any one of the following neurological disorders:
            - Intellectual disability or non-syndromic developmental delay with onset < 18y, or
            - Complex epilepsy or epileptic encephalopathy with onset < 18y
            - Progressive neurodegenerative disorder, or
            - Neuropsychiatric disorder,
        - Clinical presentation is strongly suggestive of a genetic etiology due to involvement of two or more organ systems AND the phenotype warrants evaluation of multiple genes, where:
            - WES/WGS is more practical than ordering separate single gene tests or two panels based on the differential diagnosis. For example, the patient's phenotype is suggestive of two or more syndromes identifiable through two separate panels
            - WES/WGS may preclude the need for multiple invasive procedures in the absence of this testing (eg avoid muscle biopsy)
        - The member's family history is suggestive of two or more syndromes where two diagnostic or predictive panels would be ordered for the member. For example, the patient's paternal family warrants panel testing for HBOC evaluation whereas the maternal family warrants panel testing for cardiomyopathy.

    c. A **fetus** when all of the following criteria are met:
        - Testing is performed on direct amniotic fluid or amniotic fluid/chorionic villi, cultured cells from amniotic fluid/chorionic villi or DNA extracted from fetal blood or tissue AND
        - Standard diagnostic testing by chromosomal microarray or karyotype is complete and uninformative AND
        - Two or more structural anomalies, or
        - One structural fetal anomaly with family history of disease suggesting shared etiology

        - ~~A neuropsychiatric diagnosis; **or**~~
        - ~~Complex epilepsy, including drug resistant epilepsy or epileptic encephalopathy;~~

            ~~**and at least one of the following**:~~

            - ~~Congenital abnormalities in other organ systems convey suspicion of causative gene mutation(s); **and/or**~~
            - ~~Family history conveys suspicion of causative gene mutation(s); **and/or**~~

- Intellectual disability in members who would have qualified if the WES testing had been available when they were children

and

5. Clinically indicated testing (e.g., fragile X, metabolic, etc) has not been diagnostic; **and**

6. The genetic testing results have reasonable potential to impact the clinical management and/or preventive surveillance strategies; **and**

7. The member and/or parents/legal guardians (if applicable) have been appropriately counseled about the testing by a qualified professional (same or similar to ordering providers) who is involved in the member's care.

WES Trio testing:

Testing is considered medically necessary for exome sequencing of an affected child's biological mother and/or father if the criteria is met and ANY of the following clinical situations:

- The index Individual's medical history and physical exam strongly suggest that there is an underlying genetic etiology; or
- Identification of a gene variant or mutation in an individual with a previously undiagnosed genetic syndrome; or
- Reoccurrence risk assessment

Whole Exome Sequencing Re-Analysis

Requests for the re-analysis of a previously approved whole exome sequence will be considered to be medically necessary when one of the following criteria are met:

- A minimum of 12 months has elapsed from the date of original analysis; and
- The re-analysis is being done through the original sequencing lab; and
    - Additional symptoms or clinical signs have broadened the phenotype assessed during the original exome evaluation; or
    - The birth and/or the diagnosis of a similarly affected first-degree relative has added to the pedigree analysis

LIMITATIONS:

Whole Genome Sequencing (WGS) - REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

WGS is an evolving technology, but currently has limited application outside of a research setting. Consideration of requests for WGS will be done on a "per-case" basis.

Whole genome has limited clinical utility at this time and is not recommended as a first line test. Whole genome sequencing may be a more cost-effective approach to diagnostic genetic testing when ordered in place of both chromosomal microarray AND whole exome sequencing. If either test has been ordered, consideration of requests for WGS will be done on a "per-case" basis.

Whole genome may be considered when ALL of the following criteria have been met:

- WES has not been performed, AND
- Single gene testing and/or targeted panel testing has been completed and is uninformative, AND
- Points 1 through 4 above are satisfied

EXCLUSIONS: The Plan does NOT provide coverage for the use of whole exome sequencing for indications other than those listed above because it is considered experimental, investigational or unproven. There is currently insufficient evidence in the peer-reviewed published medical literature to

~~establish the effectiveness of WES/WGS on health outcomes when compared to established tests or technologies for the following applications:~~

- ~~Preimplantation genetic testing in embryos~~
- ~~Prenatal genetic diagnosis and/or screening~~
- ~~Evaluation of fetal demise~~

There is currently insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of WES/WGS on health outcomes when compared to established tests or technologies for the following applications~~:~~

Whole exome or whole genome sequencing in the general population is considered unproven and not medically necessary, and therefore **NOT COVERED.**

Testing using whole exome or whole genome sequencing is considered unproven and not medically necessary, and therefore **NOT COVERED** for ANY of the following indications:

- Any testing using cell-free DNA
- Preimplantation testing of an embryo
- Carrier screening
- Diagnosis or prognosis of cancer

Testing of a fetus using whole exome or whole genome sequencing is considered unproven and not medically necessary, and therefore **NOT COVERED** for ANY of the following indications:

- healthy pregnancy
- isolated ultrasound soft marker(s), (eg. echogenic bowel, intracardiac echogenic focus, choroid plexus cysts)
- isolated neural tube defect, or increased nuchal translucency
- indications other than fetal structural anomalies

MP356 Genetic Testing for Mitochondrial Disorders – (Revised) – Revise Criteria

DESCRIPTION: Genetic Testing for Mitochondrial Disorders
Mitochondrial disorders may be caused by mutation of a mitochondrial DNA (mtDNA) gene or mutation of a nuclear gene (nDNA).

Mitochondrial dysfunction should be considered in the differential diagnosis of any progressive multisystem disorder. A full evaluation for a mitochondrial disorder is often warranted in individuals with a complex neurologic picture or a single neurologic manifestation and other system involvement. Mitochondrial disorders can affect most organ systems, but a particular emphasis on the neuromuscular system and cardiovascular system is important.

CRITERIA FOR COVERAGE: <u>REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE</u>

Genetic testing (whole mtDNA sequencing and deletion/duplication analysis) for mitochondrial disorders (e.g, Alpers' syndrome; Leigh syndrome; Leber's hereditary optic neuropathy (LHON); mitochondrial encephalopathy, lactic acidosis and stroke-like episodes (MELAS); Myoclonic Epilepsy and Ragged-Red Fibers (MERRF); Chronic Progressive External Ophthalmoplegia (CPEO); Kearns-Sayre syndrome) will be considered medically necessary when the following criteria are met:

- Genetic counseling by a genetics professional ~~an appropriate provider~~ has been completed; and
- ~~Appropriate~~ Relevant biochemical testing for the suspected disorder has been complete (examples: plasma or CSF lactic acid, ketone bodies, acylcarnitine, or urine organic acids) ~~is not confirmatory of a diagnosis of a specific mitochondrial condition~~; and
- Whole mtDNA testing ~~sequencing~~ has not been previously performed

- Member's clinical presentation does not fit a well-described mendelian disorder or genetic syndrome for which single-gene or targeted nDNA panel testing is available; or
- Member is being concurrently tested through whole exome sequencing
- ~~Member has altered function in two or more organ systems, and~~
- Member has one or more of the following clinical features: progressive wasting, milestone regression, ataxia, encephalopathy, seizures, developmental regression, lactic acidosis, and stroke-like episodes (MELAS), pigmentary retinopathy (NARP), mitochondrial myopathy, diabetes mellitus, sensorineural hearing loss or bilateral deafness, early-onset peripheral neuropathy, optic neuropathy, optic atrophy, ophthalmoplegia, ptosis, cardiomyopathy, heart block; OR ~~and~~
- Family history is strongly suggestive ~~s~~ mitochondrial inheritance (e.g. paternal transmission has been ruled out); and
- ~~Whole mtDNA sequencing has not been previously performed~~

MP370 Endobronchial Valve – (NEW)

DESCRIPTION:
Endobronchial Valves are implantable bronchial valves used for the bronchoscopic treatment of adults with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

INDICATIONS:

1. Endobronchial valve placement with an FDA approved device (e.g., Zephyr® or Spiration® Valve System) may be considered medically necessary for the treatment of severe emphysema when the member's dyspnea symptoms are poorly controlled, and activities of daily living are markedly restricted despite maximal medical management and completion of pulmonary rehabilitation and when **ALL** of the following criteria are met:
   - Forced expiratory volume (FEV1) is less than 45% of predicted value
   - Residual volume is greater is 180% predicted or greater
   - Total lung capacity is greater than or equal to 100% predicted;
   - 6-minute walking distance ≥100m
   - Targeted lobe shows little to no collateral ventilation (CV);
   - Abstinence from smoking of any kind for 4 consecutive months prior to initial evaluation, and throughout the evaluation for the procedure; AND
   - Body mass index (BMI) greater than 15 kg/m2 and less than 35 kg/m2.

2. Endobronchial valves may be considered medically necessary for the treatment of prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery.

EXCLUSIONS:
The use of endobronchial valves is considered investigational and therefore **NOT COVERED** when the member has any of the following:

- does not meet the coverage criteria outlined in this policy
- has previously undergone ipsilateral lung volume reductive surgery or lung/lobar transplant.
- has evidence of active pulmonary infection.
- has known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium) or silicone, unless being treated by an allergist.
- has evidence of large bullae encompassing greater than 30% of either lung**.**

The following policies have been reviewed with no change to the policy section. Additional references or background information was added to support the current policy.

MP040 Somnoplasty/ Coblation
MP049 Visual Field Testing
MP093 Uroleume
MP101 Gliasite Radiation Therapy
MP129 Total Parenteral Nutrition
MP131 VitalStim NMES
MP135 Osseointegrated Hearing Device
MP146 Sympathetic Therapy
MP150 Carotid Artery Stent
MP154 Transanal Radiofrequency Therapy for Fecal Incontinence (Secca)
MP193 Microvolt T-wave Alternans
MP213 Computerized Corneal Topography
MP229 Prolozone Therapy
MP259 Phototherapy for the Treatment of Dermatological Conditions
MP289 Dry Eye Syndrome
MP290 Fecal Microbiota Transplantation
MP342 Non-Wearable AED
MP354 Breast Pump