“What’s New” Medical Policy Updates March 2024

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

MP245 Helicobacter pylori Testing – Revised – Add Indications

INDICATIONS:
Based on guidelines of the American Gastroenterological Association (2005) and the American College of Gastroenterology (2007), carbon isotope urea breath testing (^{13}C or ^{14}C) or stool antigen testing is considered to be medically necessary in insured individuals who meet any of the following conditions:

- Active peptic ulcer disease (gastric or duodenal ulcer) or symptoms consistent with peptic ulcer disease
- Confirmed history of peptic ulcer disease and not previously treated for *H. pylori*
- Low-grade mucosa-associated lymphoid tissue (MALT) lymphoma
- Post resection of early gastric cancer
- Gastric intestinal metaplasia
- Evaluation of individuals with chronic immune thrombocytopenic purpura (ITP) and suspected H. pylori infection
- Insured individuals less than 55 years of age who have persistent dyspepsia without alarm symptoms
- To confirm eradication prior to cessation of treatment if recurrent or refractory peptic ulcer disease is present
- Pre-operative assessment prior to bariatric surgery

MP248 SNP's To Predict Risk of Non-Familial Breast CA – Revised – Expanded Description

DESCRIPTION:
Single nucleotide polymorphisms, usually referred to as SNPs, are small genetic changes among single base nucleotides.
Tests called “Polygenic Risk Scores” or PRS tests, combine the risk from Single nucleotide polymorphisms (SNPs) associated with breast cancer in Genome Wide Association Studies (GWAS). GWAS have identified over 300 SNPs among people of European origin, associated with risk for breast cancer. Some tests include combinations of SNPs and biomarkers to predict risk.

Researchers suggest that SNPs in functional regions of genes involved in sex hormone synthesis, signaling and metabolism may differentially impact breast cancer risk, depending on the person’s age or menopausal status. The available assays are designed to test for several SNPs, which are thought to predict an individual’s risk of breast cancer relative to the general population in order to identify those at increased risk who might benefit from more intensive surveillance. There are several SNP-based or PRS tests available which include but ~~is~~ are not limited to BREVAgen, OncoVue, deCODEBrestCancer, 23andMe, and Navigenics.

MP252 Colon Motility Testing – Revised – Added Exclusion

EXCLUSIONS:

Unless mandated, The Plan does **NOT** provide coverage for the use of any Colon Motility Tests not listed above (e.g., electrogastrography, electroenterography, 3D high-resolution manometry, MRI defecography) for any indication because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this modality on health outcomes when compared to established tests or technologies.

The Plan does **NOT** provide coverage for the use of a wireless capsule for measuring gastric emptying (**SmartPill® GI Monitoring System)** for all indications including but not limited to gastroparesis because it is considered **experimental, investigational or unproven.** Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this testing on health outcomes when compared to established technologies**. (See MP112 Wireless Capsule Endoscopy)**

The Plan does **NOT** provide coverage for the use of Body surface gastric mapping (Gastric Alimetry) for evaluations of gastric motility disorders and all other indications because it is unproven and Not Medically Necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this modality on health outcomes when compared to established tests or technologies.

MP255 Comparative Genomic Hybridization or Chromosomal Microarray Analysis – Revised – Revised Criteria

INDICATIONS: *Requires Prior Authorization by a Plan Medical Director or designee

Array-based comparative genomic hybridization or chromosomal microarray testing may be considered medically necessary when ordered by a Medical Geneticist*, Certified Genetic Counselor*, Pediatric Neurologist,
Neonatal Hospitalist or Developmental Pediatrician for:

Pediatric

Evaluation of chromosomal abnormalities in children when all of the following criteria are met:

1. One of the following conditions apply:
   a. Child exhibits symptoms suspected of autism spectrum disorder; or
   b. Child has a history of epilepsy or a diagnosed seizure disorder and whole exome sequencing is negative; or
   c. Whole exome sequencing was completed and negative, but a there is a high degree of clinical suspicion for a missed CNV (e.g. small del/dups can be missed, whole exome report notes CNVs were not assessed)
   d. Child exhibits symptoms of a non-syndromic developmental delay(DD), intellectual disability(ID) or loss of developmental milestones; **or**
   e. Child exhibits congenital malformation(s), anomalies or dysmorphic features that are not specific to a well delineated genetic syndrome (for which specific or targeted studies could be ordered); or
   f. Child has a suspected whole-chromosome or segmental UPD related to an imprinting disorder or to an autosomal recessive disorder; or
   g. Consanguinity of up to 3rd degree relatives has been reported, regardless of diagnosis or reported clinical history;
   h. Determine breakpoints of chromosomal rearrangements previously detected by conventional cytogenetic methods (eg. karyotype) or technologies that do not provide genome-wide coverage (eg. multi-gene panel).

And

2. Fragile X (FMR1) gene analysis (unless clinically contraindicated) is negative; **and**

3. The genetic testing results have a reasonable potential to be useful in the clinical management or preventive surveillance strategies of the child; **and**
4. The parents or legal guardians have participated in in-person genetic counseling with a licensed or certified genetic counselor; Medical Geneticist, Pediatric Neurologist or Developmental Pediatrician who are involved in the child's care.

Adults

Chromosomal microarray testing is generally not considered medically necessary in an adult for evaluation of DD/ID.

Chromosomal microarray is medically necessary in the following scenarios:
~~to~~

1. Determine breakpoints of chromosomal rearrangements previously detected by conventional cytogenetic methods (eg. karyotype) or technologies that do not provide genome-wide or CNV coverage (eg. multi-gene panel or poor or no CNV coverage with whole exome sequencing) for the purpose of accurate characterization of abnormality and additional genetic risks to member.
2. Non-invasive prenatal screening (cffDNA) indicates an abnormality may be either fetal or parental in origin. Coverage for both mother and fetus is approved in this scenario.

Prenatal & Neonatal

Chromosomal microarray testing is considered medically necessary for prenatal or neonatal use if any one of the following criteria is met:

- ~~As a diagnostic test~~ Pregnant members choosing to undergo ~~ing~~ invasive ~~prenatal~~ testing for any reason (i.e. amniocentesis, chorionic villus sampling or fetal tissue sampling) for any indication (ACOG 2016) ; or
- Non- invasive prenatal screening (eg: cffDNA) results are screen positive, inconclusive, or unreportable and ~~require~~ diagnostic confirmation is recommended; or
- Known deletion or duplication syndrome in at least one parent indicate risk to a fetus (eg: one parent has 22q11.2 deletion syndrome)
- Evaluation of a fetus with 1 or more structural abnormalities detected on fetal ultrasound; or
- Intrauterine fetal demise in any trimester ~~or third trimester stillbirth~~; or
- Parental testing is covered when a CNV is identified in a fetus or pregnancy loss; or
- Testing the products of conception following pregnancy loss at any gestational age;or
- Diagnostic testing for fetal abnormalities when the in vitro embryo is at increased risk of an inherited disorder because one of the following is documented:
    - The parents are carriers of an autosomal recessive disease; or
    - One parent is a carrier of an autosomal dominant, sex-linked, or mitochondrial disorder

MP281 Bone Morphogenetic Protein – Revised – Added Exclusion

EXCLUSIONS:

Bone morphogenetic protein (rhBMP-2 or rhBMP-7) is considered **experimental, investigational or unproven** for all other indications, including but not limited to:

- Cervical spinal fusion
- Posterior or transforaminal lumbar interbody spinal fusion
- As initial treatment or revision of non-instrumented posterolateral intertransverse spinal fusion that does not meet the criteria listed above
- As an alternative or adjunct to bone grafting in other locations, including craniomaxillofacial surgeries
- Proficient

Ceramic-Based Products [e.g., beta tricalcium phosphate (b-TCP), calcium phosphate, calcium sulfate] used alone or in
combination with other grafts including Bone Marrow Aspirate is considered to be of unproven value and therefore not medically necessary. There is insufficient evidence in the published, peer-reviewed medical literature to support the clinical value of this material compared with established alternatives . It is therefore considered to be unproven and **NOT COVERED.**

MP303 Genomic Analysis to Predict Thyroid Malignancy in FNA (Fine-Needle Aspiration) – Revised – Revised Indication

INDICATIONS:
Thyroid FNA (Fine-Needle Aspiration) Analysis (e.g., Affirma, ThyraMIR, ThyroSeq, ThyGenX, etc) is considered medically necessary when the thyroid nodule is greater than or equal to 1.0 cm and fine needle aspiration is cytologically considered to be indeterminate (eg: Bethesda category III and IV), atypical, or suspicious for malignancy.

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.

MP029 Bone Growth Stim
MP184 Intracranial Percutaneous Transluminal Angioplasty
MP192 Intensity Modulated Radiation Therapy
MP207 Corneal Hysteresis
MP211 Endovascular Repair of Intracranial Aneurysms
MP220 Epiretinal Radiation Therapy
MP226 Proton Beam Radiation
MP236 Immune Cell Function Assay for Transplant Rejection
MP237 Transurethral Radiofrequency Tissue Remodeling
MP238 Ocular Blood Flow Tonometer
MP254 Tinnitus Treatment
MP282 Termination of Pregnancy
MP285 Tonsillectomy
MP286 Cholecystectomy