“What’s New” Medical Policy Updates July 2018

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, 2018 (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within the insured individuals written benefit documents. Coverage may vary by line of business and providers and members are encouraged to verify benefit questions regarding eligibility before applying the terms of the policy.

MP033 Varicose Vein Therapy – REVISED – (Removed Exclusion)

The Plan does NOT provide coverage for Subfascial Endoscopic Perforator Surgery for the treatment of post-thrombotic syndrome or varicose veins because it is considered experimental, investigational and unproven. The effectiveness of this procedure for these indications has not been established in the current peer-reviewed published medical literature.

MP045 Chest Percussion Vest – REVISED – (Removed Prior Auth Requirement)

INDICATIONS: Requires Prior Medical Director or designee Authorization

MP089 Evaluation of Breast Ductal Lavage – REVISED – (Clarified Exclusion)

EXCLUSIONS:
The Plan does NOT provide coverage for Breast Ductal lavage which includes Fiberoptic Ductoscopy and Nipple Aspirate Fluid Suction Technique (i.e. Halo NAF System) as a means of screening or as a diagnostic tool because the current evidence does not support its use as a diagnostic test for breast cancer screening.

MP121 Wearable Cardioverter Defibrillators and Automatic External Defibrillators – REVISED – (Removed Prior Auth Requirement)

INDICATIONS: Requests for coverage require precertification by a Plan Medical Director prior to device delivery. Equipment must be obtained through contracted Durable Medical Equipment vendor(s)

MP136 Alternative Medicine Therapies – REVISED – (Removed Exclusion)

EXCLUSIONS:
Wilderness Therapy

MP299 Measurement of Serum Antibodies to Infliximab, and Adalimumab, and Vedolizumab – REVISED – (Added Exclusion)

EXCLUSIONS: Measurement of antibodies to infliximab (Remicade), or adalimumab (Humira), or vedolizumab (Entyvio) either alone or as a combination test which includes the measurement of medication serum levels, is considered experimental, investigational or unproven or is NOT COVERED.
The clinical value of these measurements for individuals receiving infliximab, vedolizumab or adalimumab therapy has not been established.

MP306 Tumor Treatment Fields – REVISED – (Removed Exclusion, Added Medicaid Business Segment)

For the Medicaid business segment, the use of TTF devices for cancer treatment may be considered for coverage through the program exception process per MCOPS Memo OPS # 05/2018-009

EXCLUSIONS:
For the Medicare business segment, the use of TTF devices for the treatment of glioblastoma multiforme or any other indication is considered not reasonable and necessary, and therefore NOT COVERED per L34823 Tumor Treatment Field Therapy.

For the Medicaid business segment, the use of TTF devices for cancer treatment is considered experimental/investigational and NOT COVERED per MCOPS Memo #06/2016-006

MP314 Molecular Testing – General Guidelines – NEW

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. Molecular testing is divided into the following categories:

Diagnostic testing (cancer): Genetic testing for the purposes of confirming the presence or absence of cancer, and may contribute information to guide prognosis and treatment options. After treatment, active monitoring is often recommended to identify if the cancer is responding to treatment, has recurred or metastasized. Specific policies may apply. See also: Genetic Testing for BRCA1/2; Genetic Testing Related to Colorectal Cancer; Gene Expression Profiling for Breast Cancer; Advanced Molecular Topographic Genotyping; Single Nucleotide Polymorphisms (SNPs) to Predict Risk of Non-Familial Breast Cancer; Microarray Gene Expression Testing for Cancer of Unknown Origin; Circulating Tumor Cells; Molecular Markers to Predict Thyroid FNA; Morphometric Tumor Analysis; Multi-gene Expression Assay for Predicting Recurrence in Colon Cancer; PCA3 and Gene Expression Assays for Prostate Cancer; Prolaris® Post-Prostatectomy Test; Proteomic Serum Analysis

Prenatal testing: Non-Invasive Testing for Fetal Aneuploidy and Microdeletions; Comparative Genomic Hybridization

Diagnostic testing (non-cancer): identifies, confirms or rules out specific conditions of chromosomal or genetic etiology. Specific policies may apply. See also: HPV DNA Testing; Janus Kinase 2 Gene Mutation Analysis; Gene Expression Testing to Predict Coronary Artery Disease; Whole Exome Sequencing; Carrier testing: Genetic testing for the purposes of carrier screening is performed to identify genetic risk that may impact reproductive decision-making. Individuals identified as being “carriers” are typically not affected by the condition but have an increased risk of having a child with a genetic condition. Genetic testing for carrier screening may be available for autosomal recessive genetic conditions, X chromosome-linked conditions, and certain other chromosomal abnormalities. Prenatal testing: detects abnormalities in a fetus’s genes or chromosomes that will result in a genetic mediated condition. Results of testing are used to guide reproductive decision-making, pregnancy management and anticipated management of the infant at birth.

Predictive or pre-symptomatic testing: detects genetic abnormalities that manifest in conditions later in life. Genetic test results may impact medical management through heightened screening strategies, preventive measures, and/or prophylactic medication. For newborn testing, state mandates apply. Specific policies may apply. See also: Non-invasive Testing for Heart Transplant Rejection

Pharmacogenetic testing: used to select appropriate treatments based on an individual’s likelihood of response or non-response, or risk of toxicity to a particular drug or therapy. Specific policies may apply. See also: Chemosensitivity and Chemoresistance Assays; Pharmacogenetic Testing; Genotyping or Phenotyping for Thiopurine Methyltransferase
COVERAGE STATEMENT
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. If coverage for genetic testing is available, specific criteria for genetic testing may be outlined in one of the related medical policies listed. If a separate policy does not exist and there is no benefit restriction, the following basic criteria apply:

In the absence of a specific policy the Plan will utilize the available peer-reviewed medical literature, independent technology assessment reports, and/or review by the Geisinger Technology Assessment Committee to evaluate the following criteria when assessing the validity and efficacy of specific genetic tests:

- The analytic validity of a test as determined by its accuracy, sensitivity and specificity to the genotype of interest
- The clinical validity of the test and its ability to confirm a diagnosis when conventional work-up is equivocal
- The clinical utility of the test measured by the degree of influence to alter the management of the individual’s care plan
- The net health outcome benefit of the test as compared to established alternatives if applicable, and the information gained is not significantly offset by physical risk, social or ethical challenges.

LIMITATIONS
Genetic testing holds great potential, it also has many limitations. Genetic tests may reveal if a mutation exists, and may predict the likelihood of developing a particular disease, but it cannot always guarantee that the disease will develop, nor can it predict how severely the disease will manifest in the individual carrying the mutation. Many genetic tests cannot detect all mutations that can cause disease, therefore while a positive result can be informative; a negative result is not always conclusive.

Coverage for genetic testing is limited to members at risk for disease or for managing a known disease.

For those reasons, genetic testing is appropriate only when offered in a setting where a licensed or certified genetic counselor* or adequately trained health care professional is able to provide appropriate pre- and post-test genetic counseling, and medical necessity is supported by ALL of the following criteria:

1. The information is needed to adequately assess risk in the member; and
2. The information will be used in the immediate care plan of the member; and
3. Pedigree analysis establishes that the insured individual is in a high-risk group for the disease; or
4. Clinical presentation of symptomology is evident and diagnosis cannot be established with conventional evaluation testing.

*A genetic counselor is considered by the Plan to be qualified if the following are met:

- M.S. or Ph.D. degree from a genetic counseling program approved/ certified by the American Board of Genetic Counseling or the American Board of Medical Genetics;
- Board certified or board qualified/eligible in the orderly process of obtaining board certification by the American Board of Genetic Counseling or American Board of Medical Genetics;
- and
- Proof of current competence and demonstrated ability (minimum of two years recent and continual experience within the past three years).

EXCLUSIONS:

- Genetic tests that do not meet the evaluation criteria for assessing the validity and efficacy
• Genetic tests for conditions which cannot be altered by treatment or prevented by interventions
• Genetic testing as a general population screening tool.
• Multiplex carrier screening tests designed to identify multiple genetic diseases in a single test
• Testing of non-covered family members
• Genetic tests that provide information that cannot reasonably be expected to elicit a change in the individual's plan of care
• Genetic testing to determine paternity or to determine the sex of an unborn child
• Direct-to-consumer genetic testing with self-administered at-home testing kits, with or without physician prescription or verbal recommendation is NOT COVERED.
• Direct-to-consumer testing in healthy persons interested in knowing if their genetic complement puts them at risk for disease is NOT COVERED.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or 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
MP017 Ambulance Transport
MP074 Interactive Metronome Training
MP084 Stereotactic Radiosurgery
MP110 Uterine Artery Embolization
MP124 Transpupillary Thermotherapy
MP134 Gastric Electrical Stimulation
MP140 Automatic Implanted Defibrillator/CRT-D with Attachment
MP141 Biventricular Pacemaker
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)
MP271 Non-Invasive Testing for Fetal Aneuploidy