“What’s New” Medical Policy Updates January 2019

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of December that will become **effective March 15, 2019** (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.

MP064 Breast Reconstruction – (Revised) – (Added Indication)

- Autologous fat harvesting and grafting as a replacement for implants in reconstructive surgery is considered medically necessary.

MP092 Implantable Cardiac Loop Recorder – (Revised) – (Added Indications)

INDICATIONS:
Members with recurrent but infrequent syncopal episodes or palpitations, when the etiology has not been diagnosed by conventional, non-invasive methods such as, but not limited to:

- Complete history and physical examination
- Electrocardiogram (ECG)
- Two negative or non-diagnostic 30-day pre-symptom memory loop patient demand recordings (e.g. Holter monitor)
- Negative or non-diagnostic tilt table testing
- Negative or non-diagnostic electrophysiological testing

Members with history of cryptogenic stroke with suspected etiology of occult atrial fibrillation when ordered by a cardiologist, electrophysiologist or neurologist: and

- The suspected cardiac arrhythmia has not been detected with standard non-invasive cardiac monitoring (either non-implantable ambulatory event monitoring or mobile cardiac outpatient telemetry).

MP108 Work Hardening/Conditioning – (Revised) – (Removed Exclusion)

EXCLUSIONS:
According to the Commission on Accreditation of Rehabilitation Facilities, work conditioning/hardening programs are used to educate and train the patient in fulfilling his/her job duties and are not designed for the treatment of an underlying condition, or for the rehabilitation of the patient towards functional independence. The Plan has determined that work conditioning/hardening programs are **NOT MEDICALLY NECESSARY** and therefore **NOT COVERED.** Specific language as may be found in the members benefit document will apply.

Functional Capacity Assessment is not covered when

- The criteria cited above are not met.
- ~~The evaluation is being performed as part of a workers compensation related evaluation~~.
- Done solely for occupational evaluation without preceding injury or illness.
- Done solely for the evaluation of eligibility for Social Security Disability benefits

MP251 Percutaneous Heart Valve Replacement – (Revised) – (Added Indications)

INDICATIONS:

Aortic Valve Replacement:

Transcatheter aortic valve replacement (TAVR) may be considered medically necessary when all of the following criteria are met:

- Diagnosis of severe aortic stenosis defined by a mean aortic valve gradient greater than 40mmHg or a jet velocity greater than 4.0m/sec, with a calcified aortic annulus
- Severe symptoms known to be secondary to the severe aortic stenosis:
  - NYHA Class III or IV heart failure; **or**
  - Syncope/ risk of sudden cardiac death; **or**
  - Refractory angina
- Member is not a candidate for open aortic valve replacement verified by two cardiovascular specialists
- No other co-morbidities limiting life expectancy to less than 1 year

Transcatheter Aortic Valve Replacement for Degenerated Bio-prosthetic Valves ("Valve-In-Valve")

TAVR for repair of a degenerated bio-prosthetic valve using an FDA-approved transcatheter heart valve system is considered medically necessary when ALL the of following criteria are met:
The member

- has a failed previous surgical bioprosthetic aortic valve; and
- is not a candidate for open surgery, or is at high risk for open surgery as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); and
- has NYHA heart failure class II, III or IV symptoms; and
- has a left ventricular ejection fraction greater than 20 percent

Pulmonary Valve Replacement:

Transcatheter pulmonary valve replacement may be considered medically necessary when the following criteria are met:

- Prior repair of congenital heart disease and right ventricular outflow tract dysfunction
- Member is not a candidate for open repair due to concomitant co-morbidities

Mitral Valve Replacement:

Transcatheter mitral valve replacement may be considered medically necessary when the following criteria are met:
The member

- Significant (Class III or IV) symptomatic, degenerative mitral regurgitation; and
- Has been determined to be at prohibitive risk as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon) and as evidenced by a Society of Thoracic Surgeons (STS) predicted operative risk score of 12 percent or greater; or the presence of a logistic EuroSCORE of 20 percent or greater.

For Medicare/Medicaid Business Segment:
The Center for Medicare & Medicaid Services (CMS) provides coverage for transcatheter mitral valve repair (TMVR) under Coverage with Evidence Development (CED) with all of the following conditions:

- The transcatheter mitral valve repair system has received FDA premarket approval (PMA) ; and
- Surgeon, cardiologist and hospital requirements are met per CMS Decision Memo CAG-00438N; and http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273 ; and
- The physician and facility are participating in a prospective, national, audited registry that meets the requirements of the CMS Decision Memo

http://www.cms.gov//medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257

Transcatheter Mitral Valve Replacement for Degenerated Bio-prosthetic Valves ("Valve-In-Valve")

TMVR for repair of a degenerated bio-prosthetic valve using an FDA-approved transcatheter heart valve system is considered medically necessary when ALL the of following criteria are met:
The member

- has a failed previous surgical bioprosthetic mitral valve; and
- is not a candidate for open surgery, or is at high risk for open surgery as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon)

EXCLUSIONS:
~~Unless mandated, the Plan does **NOT** provide coverage for percutaneous mitral valve repair or replacement by any method because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies~~.

With the exception of mandated for coverage by CMS under a Coverage with Evidence Development (CED) program, the Plan does **NOT** provide coverage for percutaneous transcatheter closure of paravalvular leaks because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies.

~~The Plan does **NOT** provide coverage for Transcatheter heart valve replacement within a failed bioprosthesis (valve-in-valve procedure) because it is considered unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies.~~

The Plan does **NOT** provide coverage for Transcatheter tricuspid valve repair (TVR) because it is considered experimental/investigational and, therefore, not covered. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies.

MP250 Bronchial Thermoplasty – (Revised) – (Added Exclusion)

EXCLUSIONS:
The Plan does NOT provide coverage for Bronchial Thermoplasty in excess of the single three-session regimen because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the safety and effectiveness of repeat treatment beyond the single three-session protocol.

MP280 Whole Exome Sequencing – (Revised) – (Expanded Indications)

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

1. Test is ordered by one of the following provider types:
   - Medical Geneticist
   - Licensed and/or Certified Genetic Counselor
   - 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 member is:
    a) ~~The~~ A child (defined as under the age of 21) who exhibits at least one of the following:
        - Autism spectrum disorder;
        - Non-syndromic developmental delay, loss of developmental milestones, or intellectual disability
        - Congenital anomalies, malformation(s), or 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 has been diagnosed with one or more of the following:
        - 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

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

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

5. 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 ~~child's~~ care.

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 this modality on health outcomes when compared to established tests or technologies.

MEDICARE BUSINESS SEGMENT:

Per Local Coverage Determination (LCD): Biomarkers Overview (L35062) exome sequence analysis is NOT COVERED, including for blood relatives.

MP312 Routine Care in Clinical Trials – (Revised) – (Clarified Indication Language)

INDICATIONS: The routine care while a member is participating in a qualifying Phase II, III, or IV clinical trial for the treatment of cancer or another life-threatening disease or condition is covered.

Routine costs in clinical trials include those items and services that:

- are typically considered to be conventional care and provided absent the clinical trial; and
- are required for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service and the prevention of complications; and
- are needed for necessary care for the diagnosis or treatment of complications.

MP321 Gene Expression Profiling for Cutaneous Melanoma – (Revised) – (Expanded Medicare Coverage)

MEDICARE BUSINESS SEGMENT:

The DecisionDx-Melanoma test is covered when the following clinical conditions are met:

- Patients diagnosed with pathologic stage sentinel lymph node biopsy (SLNB) eligible T1b and T2 cutaneous melanoma tumors with clinically negative sentinel node basins who are being considered for SLNB to determine eligibility for adjuvant therapy. (Per current NCCN and ASCO guidelines, SLNB eligible patients are defined as:
  - Patients with T1b tumors (≥ 0.8 mm or < 0.8 mm with ulceration)
  - Patients with T2 tumors

MP323 Molecular Profiling of Malignant Tumors to Identify Targeted Therapies – (NEW)

DESCRIPTION: Molecular profiling is a method for identifying multiple biomarkers in the malignant tumors of persons who have cancer. The biomarker information can be used to identify treatment options.

INDICATIONS:

REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

Molecular profiling to identify targeted therapies utilizing one of the following tests: FoundationOne, Foundation One CDx, Memorial Sloan Kettering Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT), or Target Now Molecular Profiling Service (Caris Diagnostics) will be considered medically necessary when **all of the following** criteria are met:

- A diagnosis of recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer has been established; **and**
- A decision has been made to seek further cancer treatment, such as therapeutic chemotherapy; **and**
- The member has not been previously tested using the same NGS test for the same primary diagnosis of cancer;
- The test is being used:
  - To establish eligibility for checkpoint inhibition immunotherapy including but not limited to Bavencio (avelumab), Imfinzi (durvalumab), Keytruda (pembrolizumab), Opdivo (nivolimumab), Tecentriq (atezolizumab), Yervoy (ipilimumab); **and/or**
  - As a companion diagnostic for drugs including but not limited to: Alecensa (alectinib), Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib), Erbitux (cetuximab), Gilotrif (afatinib), Herceptin (trastuzumab), Iressa (gefitinib), Kadcyla (ado-trastuzumabemtansine), Mekinist (trametinib), Perjeta (pertuzumab), Rubraca (rucaparib), Tarceva (erlotinib), Tafinlar (dabrafenib), Tafinlar (dabrafenib) in combination with Mekinist (trametinib), Tagrisso (osimertinib), Vectibix (panitumumab), Xalkori (crizotinib), Zelboraf (vemurafenib), Zykadia (ceritinib),

Molecular profiling to identify targeted therapies utilizing Guardant360 will be considered medically necessary when **all of the following** criteria are met:

The member has been diagnosed with advanced (Stage IIIB or IV) non-small cell lung cancer (NSCLC); **and**

At Diagnosis:

- The member is untreated and results for EGFR - single nucleotide variants (SNV) and indels; rearrangements in ALK and ROS1; and SNVs for BRAF AND tissue-based comprehensive somatic genomic profiling (CGP) is infeasible (i.e., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated); **or**

At Progression:

- The member is progressing on or after chemotherapy or immunotherapy and has never been tested for EGFR SNVs and indels; rearrangements in ALK, and ROS1; or SNVs for BRAF, and tissue-based CGP is infeasible (i.e. quantity not sufficient for tissue-based CGP); **or**

- The member is progressing on any tyrosine kinase inhibitors (TKI's)

EXCLUSIONS:
The Plan currently considers the use of molecular profiling tests such as, but not limited to EXaCT-1 Whole Exome Sequencing, GeneKey, GeneTrails Solid Tumor Panel, MatePair, MyAML, OmniSeq, OnkoMatch, OncInsights, and SmartGenomics to be **experimental, investigational or unproven** and **NOT COVERED.** At this time, published, peer-reviewed, medical literature to support the use of these tests is limited and insufficient to establish their analytical validity or clinical utility.

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.

MP006 Nocturnal Enuresis Alarm
MP019 Laser Tx of Cutaneous Lesions
MP055 Mastectomy for Gynecomastia
MP060 Lung Volume Reduction
MP063 Acupuncture
MP073 Deep Brain Stimulation
MP077 Noninv Mech tx for Back Pain
MP083 Contact Lenses
MP095 Craniosacral Therapy
MP099 Breast Implant Removal
MP119 Therapeutic Listening
MP123 HDR Temp Brachytherapy
MP126 Massage Therapy
MP130 Automated Amb. BP
MP138 Lysis Epidural Adhesions
MP142 Anodyne Infrared Therapy
MP149 Pulsed Electrical Stimulation for Osteoarthritis
MP155 Cooling Devices
MP168 Non-invasive Testing for Heart transplant Rejection
MP169 Retinal Prosthesis
MP186 Hip Resurfacing
MP190 Xstop Interspinous Process Decompression System

MP191 Mindstreams Cognitive Health Assessment
MP205 Advanced Molecular Topographic Genotyping
MP210 Endometrial Ablation
MP224 Topical Oxygenation
MP225 Circulating Tumor Cell Testing
MP230 Outpatient Pulmonary Rehabilitation
MP262 Microarray Based Gene Expression Testing for Cancer of Unknown Origin
MP276 Hearing Aids
MP318 Spehnopalatine Gangloin Block for Headache