

## **“What’s New” Medical Policy Updates October 2018**

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

### **MP148 Ambulatory Cardiac Event Monitors – (Revised) – (Added Exclusions)**

The following cardiac monitoring systems including but not limited to:

- BIOTRONIK biomonitor
- smartphone ECG systems ( eg, AliveCor, ViSi Mobile Monitoring System, Kardia Mobile, iHEART, ect.)

are considered **experimental, investigational or unproven** because their therapeutic value has not been established due to a lack of published evidence, and are **NOT COVERED**.

### **MP053 Cochlear Implant – (Revised) – (Added Indications)**

#### **INDICATIONS:**

**Single or multiple channel unilateral or bilateral cochlear implants** will be considered medically necessary when **ALL** of the following criteria are met:

- The member must be at least 12 months of age with bilateral, moderate-to-profound sensorineural deafness (70 decibels or greater).
- The member must be unable to benefit from a hearing aid (open sentence recognition score of 40% or less under optimal aided circumstance)
- ~~Service must be delivered by a participating provider~~
- The device must be an FDA approved cochlear implant.

In addition, certain members in the Medicare Business Segment may be eligible for cochlear implants as listed below:

- Members with hearing test scores of greater than 40% to less than or equal to 60% when the device and services are provided as part of a prospective, controlled comparative trial approved by CMS

**Hybrid cochlear implant** will be considered medically necessary when **ALL** of the following criteria are met:

- The member is 18 years of age and has a diagnosis of bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; and
- The member obtains limited benefit from appropriately fit bilateral hearing aids; and
- The following hearing thresholds are met in the ear selected for implantation:
  - Low-frequency (125 -500hz) hearing thresholds no poorer than 60 dB hearing level
  - Severe to profound mid- to high-frequency (2000 - 4000 Hz) hearing loss  $\geq$ 75 dB hearing level
  - Aided consonant-nucleus-consonant word recognition score from 10% to 60% in the preoperative aided condition
- The following hearing thresholds are met in the contralateral ear:
  - Moderately severe to profound mid-to-high frequency (2000 – 4000Hz) hearing loss greater than or equal to 60 dB hearing level; and
  - Aided consonant-nucleus-consonant word recognition score equal to or better than that of the ear selected for implantation but not more than 80 percent correct

- There are no contraindications including but not limited to **ANY** of the following:
  - Chronic or active infection of the external or middle ear or mastoid cavity in the ear selected for implantation; or
  - Tympanic membrane perforation; or
  - Evidence of agenesis of the cochlea in the ear selected for implantation; or
  - Etiology of deafness is due to lesions of the brainstem, or
  - Etiology of deafness is due to lesions of the eighth cranial nerve or central auditory pathway

### **MP059 Fetal Surgery – (Revised) – (Added Indication)**

#### **INDICATIONS: REQUIRES PRIOR MEDICAL DIRECTOR OR DESIGNEE AUTHORIZATION**

The Plan will cover fetal surgery for the following indications:

- Congenital cystic adenomatoid malformations
- Urinary tract obstruction
- Hydronephrosis
- Acardiac twins
- High risk sacrococcygeal teratomas (SCT)
- Twin reversed arterial perfusion
- **Myelomeningocele repair**
- Fetal cord ligation for twin to twin transfusion\*
  - \*only in the event of 100% predicted infant mortality without intervention

### **MP239 Pharmacogenetic Testing for Warfarin Metabolism – (Revised) – (Added Indication and Exclusions)**

#### **INDICATIONS:**

Pharmacogenetic testing is considered to be medically necessary when the identification of a specific gene marker is noted to be clinically necessary before initiation of therapy by the U.S. Food and Drug Administration as noted in the Indications section of the prescribing information. Examples include, but are not limited to any of the following:

- K-RAS for cetuximab (Erbix) and/or panitumumab (vectibix)
- BRAF for vemurafenib (Zelboraf)
- CTFR for ivacaftor (Kalydeco) or lumacaftor/ivacaftor (Orkambi)
- EGFR for cetuximab (Erbix) and/or afatinib dimaleate (Gilotrif)
- HER2/neu for trastuzumab (Herceptin) and/or lapatinib (Tykerb)
- Genotype 1 chronic hepatitis C for teleprevir (Incivik)
- ER for fulvestarnt (Faslodex)
- GBA for velaglucerase alfa
- BCR/ABL1 for dasatinib, imatinib, nilotinib, ponatinib and/or bosutinib
- PDL1 for pembrolizumab (Keytruda)
- HLA-B\*5701 for Abacavir (Ziagen)
- HLA-B\*1502 for persons of Asian ancestry prior to carbamazepine (Tegretol)
- **ALK for crizotinib (Xalkori) or ceritinib (Zykadia)**
- TPMT gene mutation or phenotypic assay for 6-mercaptopurine or azathioprine therapy (**See MP311 for additional information**)
- MGMT gene methylation assay for temozolomide (Temodar)
- NS3 Q80K for simeprevir (Olysio)

#### **EXCLUSIONS:**

Unless otherwise mandated, the Plan does **NOT** provide coverage for the use of the following pharmacogenetic testing because they are considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is

insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

- CYP2D6 gene mutation for any of the following
  - Opioid analgesics
  - Antidepressants for treatment of depression (including SSRI's) **(not applicable to Medicare)**
  - Anti-psychotics for treatment of schizophrenia
  - Tamoxifen resistance
- DPYD gene mutation for capecitabine or 5-fluorouracil
- CYP2C9 for warfarin metabolism **(not applicable to Medicare/Medicaid)**
- VKORC1 for warfarin metabolism **(not applicable to Medicare/Medicaid)**
- CYP1A2
- CYP3A4
- CYP3A5
- CYP2B6
- OPRM1 ( $\mu$ -opioid receptor)
- OPRK1 ( $\kappa$ -opioid receptor)
- DRD1 (dopamine receptor)
- DRD2 (dopamine receptor)
- DRD4 (dopamine receptor)
- DAT1 or SLC6A3 (dopamine transporter)
- DBH (dopamine beta-hydroxylase)
- SLCO1B1 genotyping to improve statin prescribing and patient adherence
- TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism)
- IFNL3 (prediction of virological response to pegylated-interferon-alpha and ribavirin combination therapy)
- MTHFR (5, 10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis
- UGT1A1 for irinotecan treatment
- UGT2B15 (uridine diphosphate glycosyltransferase 2 family, member 15)
- COMT (catechol-O-methyl-transferase)
- CYP2C19 for any of the following:
  - Clopidogrel resistance **(covered for Medicare in individuals with acute coronary syndrome. May be considered for program exception for the MA business segment as noted above)**
  - Antidepressants
  - Barbiturates
  - Proton pump inhibitors
  - Mephenytoin

### **MP296 Occipital Nerve Block – (Revised) – (Removed Prior Auth)**

**INDICATIONS:** **REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE**

### **MP322 Drug Testing in Substance Abuse Treatment – (NEW)**

**DESCRIPTION:** Drug Testing in Substance Abuse Treatment is divided into two categories: Qualitative (also known as Presumptive) and Quantitative (also known as Confirmatory) immunoassay.

**INDICATIONS:** The following drug testing is covered when criteria are met:

**Presumptive (Qualitative) Testing:** For baseline screening before initiating treatment or at the time treatment is initiated: All criteria must be met:

1. Clinical assessment of the member's history and risk of substance abuse is performed; and
2. The diagnosis, physical examination or exhibited behavior of the insured individual support the need for urine drug testing; and
3. There is a plan of care outlining how the test results will be used clinically

#### **FREQUENCY OF TESTING DURING SUBSTANCE ABUSE TREATMENT**

Stabilization phase: Although variable based on complexity of the individual member's case, the stabilization phase is typically 4 weeks for persons receiving treatment for substance abuse. During this phase, weekly testing is generally considered appropriate.

Maintenance phase: Although variable based on complexity of the individual member's case, targeted presumptive testing once every 1 to 3 months generally considered appropriate

**Confirmatory (Quantitative) testing:** All criteria must be met:

1. The presumptive test results are positive AND the confirmatory testing is limited to substances identified as present or positive on the presumptive test; AND
    - a. The confirmatory test is ordered within 24 hours of a presumptive test; OR
    - b. The presumptive test result is negative and the result is inconsistent with the member's history or presenting behavior AND the confirmatory test is ordered within 24 hours of the presumptive test.
- OR
2. The criteria for presumptive testing are met, but there is no presumptive test available (e.g., some synthetic or semi-synthetic opioids); or
  3. Immunoassays for the relevant drug(s) are not commercially available; or
  4. definitive drug levels are required for clinical decision making.

#### **LIMITATIONS:**

Drug testing, by any test method and/or combination, will be considered medically necessary up to a maximum of 20 dates of service in a calendar year when the criteria are met.

Requests for coverage in excess of 20 dates of service **REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR**, and may be considered if it is suspected that the member is continuing a pattern of substance abuse as evidenced by either of the following:

- documentation of poor compliance; or
- documentation of deteriorating function or aberrant behavior (e.g., repeated lost prescriptions, repeated early refill requests, prescriptions for controlled substances from multiple providers, unauthorized or self-dosing, unsupervised dose escalation, apparent intoxication.)

#### **FOR MEDICAID BUSINESS SEGMENT:**

Quantity limits for presumptive and definitive tests are represented by codes 80305-80307 and G0480 - G0483, and G0659, are limited to 1 per day. Testing identified by codes 80320-80377, and 83992 are also limited to 1 per day.

Drug testing utilizing oral fluid analysis is considered on a per-case basis.

## **EXCLUSIONS:**

There is insufficient evidence in the peer-reviewed, published medical literature to support the use of hair analysis as a drug testing methodology. It is therefore considered experimental, investigational or unproven and **NOT COVERED**.

There is insufficient evidence in the peer-reviewed, published medical literature to support the use of oral fluid analysis as a drug testing methodology. Unless mandated or otherwise noted, it is therefore considered experimental, investigational or unproven and **NOT COVERED**

Third-party requests for urine drug testing including but not limited to, school, employer requests, or court-ordered testing is **NOT COVERED**.

**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.**

MP024 External Counterpulsation  
MP069 Ultrafiltration  
MP080 Cardiac Rehab  
MP115 Autologous Chondrocyte Implant  
MP116 Hippotherapy  
MP117 Dry Hydrotherapy  
MP118 Quantitative Sensory Testing  
MP120 Intracavitary Balloon Brachytherapy for Breast Cancer  
MP161 Thermal Capsulorrhaphy  
MP166 MR Ultrasound Ablation of Uterine Fibroids  
MP181 Suit Therapy  
MP274 Diapers and Incontinence Supplies  
MP284 Bone Mineral Density Measurement  
MP302 Percutaneous Tibial Nerve Stimulation