“What’s New” Medical Policy Updates October 2019

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, 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.

MP053 Cochlear Implant – (Revised) – (Added Exclusion)

EXCLUSIONS:
Use of cochlear implant is contraindicated in the following:
- Deafness due to lesions of the acoustic nerve or central auditory pathway
- Otitis media or other unresolved ear problems
- Radiographic evidence of absent cochlear development

The Plan does not cover the replacement of external components with upgraded components when done solely to improve appearance or to treat psychological symptomatology or complaints because it is considered not medically necessary.

Frequency modulated (FM) systems are used as an extension or accessory of cochlear implants and are not integral to the function of the cochlear implant itself. These devices are considered not medically necessary.

MP115 Autologous Chondrocyte Implant – (Revised) – (Added Exclusion)

EXCLUSIONS: The Plan does NOT provide coverage for Autologous Chondrocyte Implantation for joint articular surfaces other than the knee because it is 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 procedure on health outcomes in joints other than the knee when compared to established tests or technologies.

Autologous chondrocyte implantation performed in combination with osteochondral autograft transfer system (hybrid ACI/OATS) is considered to be experimental, investigational or unproven for the treatment of osteochondral defects. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this procedure on health outcomes in joints other than the knee when compared to established tests or technologies.

MP239 Pharmacogenetic Testing for Warfarin Metabolism – (Revised) – (Added Indications 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 (Erbitux) and/or panitumumab (Vectibix)
- BRAF for vemurafenib (Zelboraf), dabrafenib (Tafinlar), pembrolizumab (Keytruda) or encorafenib (Braftovi)
- BRAF and NRAS for cetuximab (Erbitux) or panitumumab (Vectibix)
• CTFR for ivacaftor (Kalydeco) or lumacaftor/ivacaftor (Orkambi)
• EGFR for cetuximab (Erbitux), erlotinib (Tarceva), osimertinib (Tagrisso), and/or afatinib dimaleate (Gilotri)
• HER2/neu for trastuzumab (Herceptin) and/or lapatinib (Tykerb)
• Genotype 1 chronic hepatitis C for teleprevir (Incivik)
• ER for fulvestrant (Faslodex)
• GBA for velaglucerase alfa
• BCR/ABL1 for dasatinib, imatinib, nilotinib, ponatinib and/or bosutinib
• PDL1 for pembrolizumab (Keytruda), durvalumab (Imfinzi).
• HLA-B*5701 for Abacavir (Ziagen)
• HLA-B*5801 for allopurinol
• ALK for crizotinib (Xalkori) or ceritinib (Zykadia)
• DYPD gene mutation for capecitabine or 5-fluorouracil
• BRCA for olaparib (Lynparza), rucaparib (Rubraca)
• 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)
• FTL3 mutation assay for midostaurin (Rydapt)
• CYP2D6 for tetrabenazine (Xenazine) greater than 50 mg per day, eliglustat (Cerdelga).

Generally, pharmacogenetic testing such as mutation analysis or genotyping is considered to be medical necessary when:
• The member is a candidate for a targeted therapy as noted above; and
• The testing methodology used to investigate and identify the genetic mutation or biomarker has been proven to be clinically valid and analytically valid; and
• The test result has been proven to have clinical utility and will have a direct impact on the decision making and/or the member’s clinical outcome.

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
  o Opioid analgesics
  o Antidepressants for treatment of depression (including SSRI’s) (not applicable to Medicare)
  o Anti-psychotics for treatment of schizophrenia
  o Tamoxifen resistance
• DYPD 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 (µ-opioid receptor)
• OPRK1 (k-opioid receptor)
• DRD1 (dopamine receptor)
• DRD2 (dopamine receptor)
- DRD4 (dopamine receptor)
- DAT1 or SLC6A3 (dopamine transporter)
- DBH (dopamine beta-hydroxylase)
- SLC01B1 genotyping to improve statin prescribing and patient adherence
- TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism)
- IFNL3 (prediction of virological response to peglated-interferon-alpha and ribavirin combination therapy)
- MTHFR (5, 10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis
  - HTR2A (eg, citalopram metabolism) gene analysis, common variants
  - HTR2C (eg, citalopram metabolism) gene analysis, common variants
- 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

**MP273 Gene-based Testing and/or Protein Biomarkers for Diagnosis and Management of Prostate Cancer – (Revised) – (Added Coverage)**

**COMMERCIAL and NON-MEDICARE BUSINESS SEGMENTS**

ConfirmMDx is covered for members with negative or non-malignant abnormal histopathology findings, such as atypical cell or high-grade prostate intraepithelial neoplasia (HGPIN) on prostate biopsy, yet with high-risk factors (elevated/rising PSA or abnormal digital rectal exam) and are candidates for repeat biopsy.

Gene expression prognostic assay (eg, Prolaris, OncoType Dx) is covered for members to help determine which members with early stage, needle biopsy proven prostate cancer can be conservatively managed rather than treated with definitive surgery or radiation therapy when the following criteria are met:

1. Needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement), and
2. Formalin fixed paraffin-embedded (FFPE) prostate biopsy specimen with at least 0.5 mm of cancer length; and
3. Stage as defined by the one of the following:
   - Very Low Risk Disease (T1c AND Gleason Score ≤ 6 AND PSA ≤ 10 ng/mL AND <3 prostate cores with tumor AND ≤ 50% cancer in any core AND PSA density of < 0.15 ng/mL/g) OR
   - Low Risk Disease (T1-T2a AND Gleason Score ≤ 6 AND PSA ≤ 10 ng/mL), and
4. The member has an estimated life expectancy of greater than or equal to 10 years, and
5. The member is a candidate for and is considering conservative therapy and yet would be eligible for definitive therapy (radical prostatectomy, radiation therapy or brachytherapy), and
6. Result will be used to determine treatment between definitive therapy and conservative management.
OncoType DX AR-V7 assay is covered when the following criteria are met:

1. The member is diagnosed with progressive mCRPC as defined by the Prostate Cancer Working Group 2 guidelines (a minimum of 2 rising prostate-specific antigen (PSA) levels 1 or more weeks apart, new lesions by bone scintigraphy, and/or new or enlarging soft tissue lesions by computed tomography or magnetic resonance imaging; and

2. The member has experienced failure on one androgen receptor signaling inhibitor (ARSi), (e.g., Enzalutamide (Xtandi), Apalutamide (Erleada), or Abiraterone (Zytiga); and

3. The member is considered to be appropriate for treatment by their treating physician for the alternative ARSi as a single agent; and

4. Circulating tumor cells with nuclear expression of AR-V7 protein will be assessed prior to initiation of therapy.

MEDICARE BUSINESS SEGMENT:

PCA3 Assay (e.g., Progensa,) is covered for members to help determine the need for repeat prostate biopsies in members who have had a previous negative biopsy.

Palmetto GBA a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies and establishes the coverage policy for Medicare beneficiaries has determined that ConfirmMDx is covered in members with previous negative prostate biopsy who are being considered for repeat biopsy when the following criteria are met:

- Males aged 40 to 85 years old that have undergone a previous cancer-negative prostate biopsy within 24 months and are being considered for a repeat biopsy due to persistent or elevated cancer-risk factors, and
- The previous negative prostate biopsy must have collected a minimum of 8 tissue cores (but not have received a saturation biopsy of > 24 tissue cores) and remaining FFPE tissue from all cores is available for testing, and
- Minimum tissue volume criteria of 20 microns of prostate biopsy core tissue is available (40 microns preferable), and
- Previous biopsy histology does not include a prior diagnosis of prostate cancer or cellular atypia suspicious for cancer (but may include the presence of high-grade prostatic intraepithelial neoplasia (HGPIN), proliferative inflammatory atrophy (PIA), or glandular inflammation), and
- Member is not being managed by active surveillance for low stage prostate cancer, and
- Tissue was extracted using standard patterned biopsy core extraction (and not transurethral resection of the prostate (TURP)), and
- Member has not been previously tested by ConfirmMDx from the same biopsy samples or similar molecular test.

Palmetto GBA a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies and establishes the coverage policy for Medicare beneficiaries has determined that Decipher Biopsy Prostate Cancer Classifier Assay is covered for Men with Favorable Intermediate Risk Disease and with Unfavorable Intermediate Risk Disease when the following criteria are met:

A. Favorable Intermediate Risk Disease Criteria:
- Needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement), and
- FFPE prostate biopsy specimen with at least 0.5 mm of cancer length, and favorable intermediate risk disease defined as:
  - Gleason Grade Group 2 (Gleason Sum 3+4=7); and
  - Estimated life expectancy of greater than or equal to 10 years, and
• Member is a candidate for and is considering conservative management and yet would be eligible for definitive therapy (radical prostatectomy, radiation or brachytherapy), **and**
• Result will be used to determine treatment between definitive therapy and conservative management, **and**
• Member has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **and**
• Member is monitored for disease progression according to established standard of care

B. Unfavorable Intermediate Risk Disease Criteria:
• Needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement), **and**
• FFPE prostate biopsy specimen with at least 0.5 mm of cancer length, and unfavorable risk disease defined as:
  - Gleason score 3+4=7 / grade group 2 or Gleason score 4+3=7 / grade group 3, **or**
  - T2b to T2c, **or**
  - PSA 10-20 ng/mL, **and**
• Estimated life expectancy of greater than or equal to 10 years, **and**
• Member is a candidate for definitive therapy (RP +/- PLND, EBRT + ADT, or EBRT + brachytherapy +/- ADT), **and**
• Result will be used to determine treatment between definitive therapy modality, **and**
• Member has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **and**
• Member is monitored for disease progression according to established standard of care

Palmetto GBA a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies and establishes the coverage policy for Medicare beneficiaries has determined that OncoType DX AR-V7 assay is covered when the following criteria are met:

1. The member is diagnosed with progressive mCRPC as defined by the Prostate Cancer Working Group 2 guidelines (a minimum of 2 rising prostate-specific antigen (PSA) levels 1 or more weeks apart, new lesions by bone scintigraphy, and/or new or enlarging soft tissue lesions by computed tomography or magnetic resonance imaging; and
2. The member has experienced failure on one androgen receptor signaling inhibitor (ARSi), (e.g., Enzalutamide (Xtandi), Apalutamide (Erleada), or Abiraterone (Zytiga); and
3. The member is considered to be appropriate for treatment by their treating physician for the alternative ARSi as a single agent; and
4. Circulating tumor cells with nuclear expression of AR-V7 protein will be assessed prior to initiation of therapy

MP306 Tumor Treatment Fields – *(Revised) – (Added Medicare Coverage)*

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

**COMMERCIAL AND MEDICARE BUSINESS SEGMENTS:**

ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are **NOT SEPARATELY REIMBURSABLE**.

The Optune™tumor treatment field delivery system may be considered medically necessary when all of the following criteria are met:
1. As concomitant therapy with temzolomide in newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy; and
   • Member is an adult (defined by the FDA for this device as age 22 years or older); and
   • Karnofsky Performance Scale* score of 60 (70 for Medicare) or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; and
   • Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day

or

2. As a monotherapy for recurrent histologically- or radiologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain after receiving chemotherapy;
   • Member is an adult (defined by the FDA for this device as age 22 years or older); and
   • Karnofsky Performance Scale* score of 60 (70 for Medicare) or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; and
   • Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day

MP328 Genetic Susceptibility Cancer Panels – (NEW)

DESCRIPTION: Hereditary cancer syndromes are a group of disorders in which the presence of one or a combination of gene variants have been shown to increase the risk for the development of specific cancers. Genetic cancer susceptibility panel testing using next generation sequencing will be considered to be medically necessary when the medical criteria outlined in this policy are met.

INDICATIONS:
For members presenting with clinical features and/or has a family history consistent with a hereditary cancer syndrome related to BRCA, please refer to MP097 Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer

For members presenting with clinical features and/or has a family history consistent with a hereditary cancer syndrome related to Lynch syndrome and Familial Adenomatous Polyposis, please refer to MP098 Genetic Testing Related to Colorectal Cancer

Genetic testing with a multi-gene cancer panel is considered medically necessary in members who have previously tested negative or indeterminate for the high penetrance genes that are most likely to explain the personal or family history of when ALL of the following criteria are met:
   • The suspected hereditary cancer syndrome(s) can be diagnosed by one or more of the genes included in the requested hereditary cancer panel; and
   • The results of testing will directly impact the member’s clinical management; and
   • The member’s personal and family history is suggestive of an inherited susceptibility that can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel including at least one of the following:
     o A personal history of at least two different cancers
     o A personal history of cancer diagnosed at age 40 or younger
     o A personal history of cancer and at least one first, second- or third-degree blood relative with a cancer associated with Lynch Syndrome (i.e.,brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal, small intestine, or ureter cancers, sebaceous adenomas, or sebaceous carcinomas)
     o At least one first, second, or third-degree blood relative diagnosed with breast, ovarian, prostate or pancreatic cancer at age 40 or younger
     o At least three first, second, or third-degree blood relative on the same side of the family diagnosed with any cancer

EXCLUSIONS: Multi-gene hereditary cancer panels are unproven and not medically necessary for general population screening, and all other indications not meeting the criteria outlined in this policy.
**MP329 Genicular Nerve Ablation – (NEW)**

**DESCRIPTION:** Genicular Nerve Ablation (e.g., radiofrequency (RFA), pulsed radiofrequency, cooled radiofrequency (COOLIEF) cryoablation, cryoneurolysis or chemical neurolysis (chemodenervation)) has been proposed as a treatment for chronic knee pain due to osteoarthritis that have not been effectively managed by pharmacologic or other standard therapies or as a treatment to control pain pre or post knee replacement.

**EXCLUSIONS:** The Plan does NOT provide coverage for genicular nerve ablation because it is 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.

**MP330 Responsive Neurostimulation – (NEW)**

**DESCRIPTION:** The Responsive Neurostimulation System (RNS) is used to treat adult members with partial onset epilepsy who have failed treatment with at least 2 seizure medications and who are not candidates for resection of their seizure focus. About one-third of members with epilepsy have seizures that are poorly controlled with medications alone. Members are considered candidates for RNS after comprehensive diagnostic testing that has localized one or two seizure foci, but are determined not to be candidates for surgical resection for a particular reason. These reasons include seizures that originate from more than one area of the brain, seizures that arise from areas of the brain that cannot be resected without causing a deficit, or seizures that are difficult to discretely localize.

**INDICATIONS:** Responsive Neurostimulation will be considered medically necessary when ALL of the following criteria are met:

- Diagnosis of focal (aka, partial) epilepsy has been established; **and**
- The member is 18 years or older; **and**
- Medical record documentation of failure of two (2) or more antiepileptic medications; **and**
- No more than two (2) well-localized foci have been identified by diagnostic testing; **and**
- The member experiences an average of three (3) or more disabling seizures per month over the prior three months; **and**
- The member is not a candidate for a focal resection of the epileptogenic foci; **and**
- There is no evidence of a rapidly progressive neurologic disorder; **and**
- There is no evidence of a primary generalized epilepsy

**LIMITATIONS:**
The replacement/revision of a responsive neurostimulator is considered medically necessary for members who meet all of the above criteria, when the existing device is no longer under warranty and cannot be repaired.

**EXCLUSIONS:** The Plan does NOT provide coverage for Responsive Neurostimulation for any diagnosis other than those listed above 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.

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
MP059 Fetal Surgery
MP069 Ultrafiltration
MP080 Cardiac Rehab
MP116 Hippotherapy
MP117 Dry Hydrotherapy
MP118 Quantitative Sensory Testing
MP120 Intracavitary Balloon Brachytherapy for Breast Cancer
MP161 Thermal Capsulorraphy
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