“What’s New” Medical Policy Updates December 2020

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the months of November that will become **effective January 15, 2021** (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.

MP056 Management of Excessive Skin and Subcutaneous Tissue – (Revised) – Add labiaplasty exclusion

EXCLUSIONS:
Members may **NOT** be eligible for surgical management of excessive skin and subcutaneous tissue for any indications other than those listed above, including but not limited to:

- Restorative or reconstructive surgery performed for cosmetic purposes and from which no significantly improved physiologic function as determined by the Plan is anticipated, is **NOT COVERED**.

- Repair of a diastasis, defined as a thinning of the anterior abdominal wall fascia, in the absence of a true midline (ventral) hernia, is not considered medically necessary because it is not associated with conditions of clinical significance.

- Solely to treat back pain, or when performed in conjunction with abdominal or gynecological procedures (e.g. abdominal hernia repair, hysterectomy), unless the above criteria for panniculectomy or abdominoplasty are met separately.

The Plan does not provide coverage for abdominal suction-assisted lipectomy or liposuction because it is considered cosmetic and **NOT COVERED.**

The Plan does not provide coverage for labiaplasty for indications other than gender reassignment or surgical reconstruction following trauma or surgical treatment of disease (e.g., oncological surgery). Other indication for labiaplasty are considered cosmetic and **NOT COVERED**.

MP121 Wearable Cardioverter Defibrillators and Automatic External Defibrillators – (Revised) – Clarified wall-mounted AED coverage and exclusion

NON-WEARABLE AED:
INDICATIONS: The member must meet criteria A and B or criteria C

Criteria A: the member has one of the following conditions:

- A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
- A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause; or
- Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrythmias such as long QT syndrome or hypertrophic cardiomyopathy; or

- Coronary artery disease with a documented prior myocardial infarction with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;
    - The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
    - The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
- Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30.
- Ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%.
- Nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%
- Members who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure

AND

B. Implantation surgery or wearable AED is contraindicated; **OR**

C. A previously implanted defibrillator now requires explantation

LIMITATIONS: For lines of business with Durable Medical Equipment benefit, coverage will be subject to the limitations or exclusions expressed in the applicable benefit document.

EXCLUSIONS: Members must not have:

1. cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; **or**
2. had an enzyme-positive myocardial infarction within the past month; **or**
3. clinical symptoms that would make them a candidate for coronary revascularization; **or**
4. irreversible brain damage from a pre-existing cerebral disease; **or**
5. any disease other than cardiac disease associated with a likelihood of survival less than one year.

The Plan does **NOT COVER** a home-based automatic external defibrillator unit in the absence of medical necessity review meeting criteria outlined above because it is considered to be a precautionary safety device to address a possible cardiac event, and not used for active treatment.

MP168 Non-invasive Testing for Heart Organ Transplant Rejection – (Revised) – Revise Title; Add Medicare coverage for renal transplant

INDICATIONS:

Heart Transplant Testing

AlloMap and AlloSure Heart Transplant Testing

For COMMERCIAL BUSINESS SEGMENT:

AlloMap testing is considered medically necessary when the following criteria are met:

- The member is 15 years of age or older; and
- The member is between 6 months and 5 years post-transplant; and
- The member is otherwise clinically stable and without overt evidence of acute rejection; and
- The member is has not received high dose steroids within the preceding 21 days; and

- The member has not received blood transfusion or hematopoietic growth factor within the preceding 30 days

AlloSure Heart [donor-derived cell-free DNA (dd-cfDNA)] is covered when used in conjunction with AlloMap® to assess the probability of allograft rejection in heart transplant recipients with clinical suspicion of rejection and to inform clinical decision-making about the necessity of a heart biopsy in such patients at least 55 days post-transplant in conjunction with standard clinical assessment.

For MEDICARE AND MEDICAID BUSINESS SEGMENTS:
CMS directives allows AlloMap, an In Vitro Diagnostic Multivariate Index assay (IVDMIA) test service performed in a single laboratory to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment. Palmetto GBA established a formal coverage policy for all Medicare patients. This local carrier determination is applicable nationally.

Renal Transplant Testing

AlloSure Kidney Transplant

For MEDICARE BUISNESS SEGMENTS:

AlloSure Kidney [donor-derived cell-free DNA (dd-cfDNA)] is covered to assess the probability of allograft rejection in kidney transplant recipients with clinical suspicion of rejection and to inform clinical decision-making about the necessity of renal biopsy in such patients at least 2 weeks post-transplant in conjunction with standard clinical assessment.

Prospera Renal Transplant Testing

For MEDICARE BUISNESS SEGMENTS:

The Prospera assay is covered only when the following clinical conditions are met:

- First time renal allograft recipients; and
- Physician-assessed pretest need to further evaluate the member for the probability of active renal allograft rejection

EXCLUSIONS: The Plan does **NOT** provide coverage for Heartsbreath breathing test for heart transplant rejection detection 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.

With the exception of CMS mandated coverage, the Plan does **NOT** provide coverage for the use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after kidney transplantation (e.g., Prospera), including but not limited to the detection of acute transplant rejection 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.

MP321 Gene Expression Profiling for Cutaneous Melanoma – (Revised) – add PLA testing

COMMERCIAL AND MEDICARE BUSINESS SEGMENT:

Gene expression profiling for cutaneous melanoma utilizing the DecisionDx-Melanoma test is considered medically necessary when the following criteria are met:

- Patients diagnosed with pathologic stage sentinel lymph node biopsy (SLNB) eligible T1b and ~~T2~~ T1a 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 T1a tumors:
        - in whom there is significant uncertainty about the adequacy of microstaging (positive deep margin), or
        - with Breslow depth <0.8 mm and with other adverse features (eg. very high mitotic index [≥2/mm2], lymphovascular invasion, or a combination of these factors)
    - Patients with T1b tumors (≥0.8 mm or < 0.8 mm with ulceration)
    - Patients with T2 tumors

COMMERCIAL AND MEDICARE BUSINESS SEGMENT:

Gene expression profiling for cutaneous melanoma utilizing the Pigmented Lesion Assay RNA gene expression test on skin samples obtained via adhesive patches is considered medically necessary when the following criteria are met:.

- The lesion must meet one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving)*
- Primary melanocytic skin lesions is between 5mm and 19mm
- Lesion skin is intact (i.e. non-ulcerated or non-bleeding lesions)
- Lesion does not contain a scar or has been previously biopsied
- Lesion is not located in areas of psoriasis, eczema or similar skin conditions
- Lesion has not already been diagnosed as melanoma or for which the clinical suspicion is sufficiently high that the treating clinician believes melanoma is a more likely diagnosis than not
- Lesion is located in areas other than palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed.

*ABCDE criteria:
Asymmetry - The shape of one half does not match the other half.
Border that is irregular - The edges are often ragged, notched, or blurred in outline. The pigment may spread into the surrounding skin.
Color that is uneven - Shades of black, brown, and tan may be present. Areas of white, gray, red, pink, or blue may also be seen.
Diameter - There is a change in size, usually an increase. Melanomas can be tiny, but most are larger than 6 millimeters wide (about 1/4 inch wide).
Evolving - The mole has changed over the past few weeks or months.

MP341 TissueCypher® Barrett's Esophagus Assay – (NEW)

DESCRIPTION:

The TissueCypher® Barrett's Esophagus Assay is a laboratory test to help identify individuals who are appropriate candidates for minimally invasive endoscopic eradication therapy by predicting development of high-grade dysplasia and esophageal adenocarcinoma in patients with Barrett's esophagus. This multi-analyte assay and analysis evaluates the expression of nine specific protein-based biomarkers and morphology-based biomarkers in the context of tissue architecture in esophageal biopsies obtained

during an upper GI endoscopy and reports the probability of progression to esophageal adenocarcinoma within five years of the endoscopy.

INDICATIONS:
TissueCypher is considered medically necessary for the evaluation of esophageal pinch biopsies (or EMR specimens) of patients confirmed to have Barrett's esophagus with histology of no dysplasia, indefinite for dysplasia, or low-grade dysplasia.

EXCLUSIONS:

All of the following services are considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the safety and effectiveness of these services on health outcomes when compared to established treatments or technologies.

- esophageal microbiota evaluation for detection of Barrett's Esophagus
- Evaluation of mitochondrial DNA deletions for detection of Barrett's Esophagus
- SOX2 expression testing for prediction of neoplastic progression in Barrett's Esophagus
- Use of markers of intestinal phenotype (CDX2, Das-1, Hep Par 1, SOX9, and villin)
- Use of mucin glycoprotein immunostains
- Use of mutation analysis for risk assessment and diagnosis of Barrett's Esophagus

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.

MP015 Experimental/Investigational
MP038 Oral Health
MP051 Vagus Nerve Stimulation
MP060 Lung Volume Reduction
MP105 Phototherapy for SAD
MP157 Prothrombin Time Home Testing
MP162 Salivary Hormone Testing for Menopause and Aging
MP164 Laser Treatment for Acne
MP177 Sensory Integration Therapy
MP194 Rhinophototherapy
MP219 Percutaneous Neuromodulation Therapy
MP225 Circulating Tumor Cell Testing
MP260 Canaloplasty and Viscocanalostomy
MP261 Aqueous Drainage Shunt
MP270 Ocular Photoscreening
MP295 Sacroiliac Joint Injection
MP296 Occipital Nerve Block
MP297 Suprascapular Nerve Block
MP300 Digital Breast Tomosynthesis
MP301 Sacroiliac Joint Fusion
MP331 Inpatient Rehabilitation
MP332 Skilled Nursing Facility