“What’s New” Medical Policy Updates February 2018

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

MP063 Acupuncture - REVISED – (clarified Exclusion Language)

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

- Radiculopathy
- Reflex sympathetic dystrophy
- TMJ pain
- Chronic intractable headache
- Peripheral neuropathy
- Back pain which is refractory to traditional treatment
- Chemotherapy-induced nausea and vomiting

Note: Additional indications may be available for some groups as determined in their contract specific benefit documents.

LIMITATIONS: Providers must be licensed by the Pennsylvania Board of Medicine in accordance with § 18.12 and § 18.13, section 3 of the Acupuncture Licensure Act (63 P.S.§ 1803); and section 8 of the Medical Practice Act of1985 (63 P.S. § 422.8).

EXCLUSIONS:

Any indication not specifically listed in this policy.

The Plan does NOT provide coverage for dry needling 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 therapy on health outcomes when compared to established tests or technologies.

Medicare, ~~Medicaid~~**, Federal Employee Health Benefits** – acupuncture 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.

PROCESS: ~~**Requires Prior Medical Director or designee Authorization**~~

MP064 Breast Reconstruction - REVISED – (clarified Exclusion Language)

DEFINED BENEFIT: Coverage for post trauma and/or post-mastectomy breast reconstruction surgery is in accordance with any and all state and/or Federal mandates, including The Women’s Health and Cancer Rights Act, which currently includes:

- Reconstructive breast surgery, in all stages, on the diseased breast as a result of mastectomy, or lumpectomy resulting in significant deformity. Covered procedures include mastopexy, insertion of breast prostheses, the use of tissue expanders, or reconstruction with a latissimus dorsi

myocutaneous flap, transverse rectus abdominis myocutaneous (TRAM) flap, superficial inferior epigastric perforator (SIEP) flap, superficial inferior epigastric artery (SIEA) flap, deep inferior epigastric perforator (DIEP) flap, or similar procedure, , Ruben's flap, superior or inferior gluteal free flap, transverse upper gracilis (TUG) flap, , superior gluteal artery perforator (SGAP) flap, profunda artery perforator flap, or similar procedures, including skin sparing techniques.associated nipple and areolar reconstruction and tattooing of the nipple area. ~~Reduction mammoplasty and related reconstructive procedures on the unaffected side for symmetry are also covered~~.

- Acellular dermal matrix products (such as but not limited to AlloDerm, DermaMatrix, FlexHD, AlloMax, DermACELL Strattice and SeriSurgical Scaffold) are covered for post mastectomy breast reconstruction

- Surgery on the non-diseased breast (reduction or augmentation) to establish symmetry between the two breasts.

~~Covered procedures include mastopexy, insertion of breast prostheses, the use of tissue expanders, or reconstruction with a, transverse rectus abdominis myocutaneous (TRAM) flap, , deep inferior epigastric perforator (DIEP) flap, or similar procedure, including skin sparing techniques.associated nipple and areolar reconstruction and tattooing of the nipple area. Reduction mammoplasty and related reconstructive procedures on the unaffected side for symmetry are also covered~~.

- Prosthesis (either implanted or external) and treatment of physical complications at all stages of the mastectomy including lymphedema
    - Removal and replacement of a ruptured breast implant (either silicone or saline) is reconstructive for implants inserted following mastectomy.
- Lymphedema treatments considered medically necessary include:
    - Complex Decongestive Physiotherapy
    - Lymphedema pumps
    - Compression lymphedema sleeves (not applicable to Medicare beneficiaries)

- Reconstructive breast surgery in members with congenital absence or significant deformity secondary to Poland syndrome

Benefits for post mastectomy reconstruction following a prophylactic mastectomy in the absence of active disease, but which is considered medically necessary based on projected risk assessment (e.g. BRCA testing, etc.) will be eligible to the extent described in this policy.

LIMITATIONS:
Areola and/or nipple tattooing is covered when provided by a licensed medical provider, operating within their scope of practice.

Nipple tattooing may be repeated once, after the initial procedure.

EXCLUSIONS:
Breast reconstruction for cosmetic reasons unrelated to trauma or mastectomy/lumpectomy is **NOT COVERED**.

MP077 Noninv Mech tx for Back Pain - REVISED – (clarified Exclusion Language)

EXCLUSIONS:
There is currently insufficient evidence in the published, peer reviewed medical literature to show the medical efficacy of devices such as, but not limited to those listed in this policy. At this time, utilization of

any of the following devices is considered **experimental, investigational or unproven** and is **NOT COVERED**.

- *Quantitative muscle testing and treatment devices* (e.g. Med-X Lumbar/Cervical Extension Machine, Isostation B 2000 Lumbar Dynamometer)
- *Vertebral Axial Decompression* (e.g. Vax-D, DRX Decompression Systems, DTS Spinal Decompression Therapy, Decompression Reduction Stabilization (DRS) System, IDD Therapy, Lordex Spinal Decompression Unit, SpineMED® Decompression, Accu-SPINA System, Antalgic-Trak, Ever-Trac ET-800, Dynatron 900, Integrity Spinal Care System, Rich-Mar Spina-Mobilizor, Triton ® DTS / Tru-Trac/ TX Traction System
- *Patient-operated spinal unloading devices* (e.g. Orthotrac™ Pneumatic Vest)

MP168 Non-invasive Testing for Heart Transplant Rejection - REVISED – (clarified Exclusion Language)

INDICATIONS:

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

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.

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

~~Unless mandated by state or federal legislation, the Plan does **NOT** provide coverage for Allomap gene expression profiling to monitor acute heart 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~~.

MP190 X-stop Interspinous Process Decompression System - REVISED – (clarified Exclusion Language)

MEDICARE BUSINESS SEGMENT:
For Medicare beneficiaries, lumbar interspinous process decompression may be considered medically necessary when all of the following criteria are met:

- The member has neurogenic intermittent pain or weakness radiating from the lumbar region into the legs as a result of a confirmed diagnosis of lumbar spinal stenosis; and

- The member has moderately impaired function and experiences relief from leg, buttock, or groin pain, with flexion; and
- The member has undergone at least six months of non-operative treatment (e.g., physical therapy, non-steroidal anti-inflammatory medication) and is a candidate for operative treatment at no more than two lumbar levels.

EXCLUSIONS:
Unless mandated, the Plan does **NOT** provide coverage for Interspinous Distraction Technology including but not limited to the *X STOP® Interspinous Process Decompression System* 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.

For the Medicare Business Segments – CMS directives may allow these devices to be considered for coverage when used in a hospital outpatient setting. Effective January 1, 2007, the new device pass-through code, C1821, includes device costs for single- and double-level treatments, and is applicable nationally.

MP250 Bronchial Thermoplasty - REVISED – (clarified Exclusion Language)

DESCRIPTION:
Bronchial Thermoplasty is a procedure believed to treat severe persistent asthma in patients whose asthma is not well controlled with conventional drug therapy. The procedure uses thermal energy (radiofrequency) to reduce airway smooth muscle mass to reduce the airway's ability to constrict. Bronchial thermoplasty is delivered in a series of three treatment sessions with a recovery period of three weeks or longer between sessions. Researchers believe that the less constriction in the airways could lead to reduced severity and frequency of asthma symptoms.

REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR or Designee

COMMERCIAL BUSINESS SEGMENT

Bronchial Thermoplasty may be considered medically necessary on a "per-case" basis for members who meet all of the following criteria:

- The member is 18 years of age or older; and
- A diagnosis of severe, persistent asthma has been established; and
- The member has documented inadequate asthma control with current maximized inhaled corticosteroids and long acting beta agonists; and
- The member is a non-smoker or has not smoked for at least one year; and
- The member has failed, is intolerant to, or is not a candidate for anti-IgE therapy or anti-Interleukin (Il)-5 therapy; and
- The member has been managed by and bronchial thermoplasty is recommended by an asthma specialist (eg, pulmonologist or allergist/immunologist)

Medicare~~/Medicaid~~ Business Segment

CMS has assigned a transitional "pass-through" status to the codes assigned to the procedure of bronchial thermoplasty and the specialized catheter used for this procedure during the bronchoscopy**.** Coverage will be limited to treatment of severe persistent asthma in patients whose asthma is not well controlled with conventional drug therapy~~., and limited to these business segments~~.

Medicaid Business Segment

Bronchial Thermoplasty may be considered on a "per-case" basis through the Program Exception process.

EXCLUSIONS:
~~Unless mandated,~~ The Plan does **NOT** provide coverage for ~~the use~~ uses of Bronchial Thermoplasty other than the treatment of severe, persistent, treatment-refractory asthma 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 modality on health outcomes when compared to established tests or technologies.

MP251 Percutaneous Heart Valve Replacement - REVISED – (clarified Exclusion Language)

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

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 Repair:

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

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.

MP318 Sphenopalatine Ganglion Block for Headache - NEW

DESCRIPTION: Sphenopalatine ganglion (SPG) nerve block via an intranasal topical anesthetic has been proposed as a treatment for chronic migraine and severe non-migraine headache. The SPG is located behind the bony structures of the nose and is linked to the trigeminal nerve, the primary nerve involved in headache disorders. The SPG has both autonomic and sensory nerves associated with pain perception. SPG blocks involve topical application of local anesthetic to mucosa overlying the SPG. It is proposed that local anesthetics in low concentrations could block the sensory fibers and reduce pain while maintaining autonomic function.

EXCLUSIONS: The Plan does **NOT** provide coverage for the use of sphenopalatine ganglion block in the treatment of headache because it is considered **experimental, investigational or unproven**. Although the catheters used to administer the anesthetic agent are FDA approved, 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.

MP006 Nocturnal Enuresis Alarm
MP019 Laser Tx of Cutaneous Lesions
MP038 Oral Health
MP055 Mastectomy for Gynecomastia
MP060 Lung Volume Reduction
MP073 Deep Brain Stimulation
MP083 Contact Lenses
MP095 Craniosacral Therapy
MP099 Breast Implant Removal
MP108 Work Hardening/Conditioning
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
MP169 Retinal Prosthesis
MP186 Hip Resurfacing
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
MP312 Routine Care in Clinical Trials