

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

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

### **MP038 Oral Health – REVISED – (clarified Auth Requirement for IWT)**

#### • **Impacted Wisdom Teeth**

For members in which applicable benefit documents include the Impacted Wisdom Tooth rider, the benefit is limited to those services that are expressly outlined in the applicable benefit document.

**CHIP and Medicaid Business Segment: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE**

### **MP075 Tissue Engineered Skin Substitutes – REVISED – (Removed Exclusion Language)**

#### **EXCLUSIONS:**

The use of tissue engineered skin equivalents in any application outside of the current FDA approvals is considered **experimental, investigational or unproven** and is **NOT COVERED**.

### **MP158 Continuous Passive Motion – REVISED – (clarified Indication Language)**

**INDICATIONS: Continuous Passive Motion devices require pre-certification by a Plan Medical Director or designee**

When used as an adjunct to active post-surgical care in the early phase of rehabilitation, continuous passive motion devices are considered *medically necessary* for up to 21 days postoperatively for the following procedures

- Members who have undergone total knee replacement or manipulation (including revision), **intra-articular cartilage repair procedures of the knee**, or surgical repair of the anterior cruciate ligament; **or**
- Members who have undergone surgery or manipulation of the articular cartilage of the shoulder or elbow

### **MP236 Immune Cell Function Assay for Transplant Rejection – REVISED – (clarified Coding Language)**

**CODING ASSOCIATED WITH: Immune Cell Function Assay for Transplant Rejection**

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

**86352 Cellular function assay involving stimulation (eg, mitogen or antigen) and detection of biomarker (eg, ATP) note: this code is not covered when used to identify Immuknow™ testing.**

## **MP245 Helicobacter Pylori Testing – REVISED – (clarified Exclusion Language)**

### **EXCLUSIONS:**

Testing for *H. pylori* is considered not medically necessary and **NOT COVERED** when used for the following:

- Screening of asymptomatic individuals;
- Serology-based testing is considered not medically necessary and is **NOT COVERED**. The ACG and AGA recommendations stress the need to eliminate the use of serology testing, and to test, treat, and retest to confirm eradication by utilizing active H pylori infection testing. Serologic testing which does not test for active infection is no longer recommended for diagnosing, monitoring infection or confirming the eradication of *H. pylori* and should no longer be used.

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

Coverage may be allowed by exception. Serology should not be performed in areas of low *H. pylori* prevalence. If performed, positive results should be confirmed with a test for active infection prior to initiating eradication therapy.

## **MP252 Colon Motility Testing – REVISED – (clarified Language)**

### **DESCRIPTION:**

Colonic motility studies are used to assess the flow of intraluminal contents, the motions of the colonic wall that induce flow, and the control systems that integrate and regulate these processes. Most approaches consist of manometric techniques to record colonic contractions, barostatic methods to measure colonic tone, and recordings of myoelectric signals from the colon that initiate and control muscular contractions.

### **MEDICAID BUSINESS SEGMENT:**

Colon motility may be considered medically necessary.

### **EXCLUSIONS:**

**Unless mandated**, The Plan does **NOT** provide coverage for the use of Colon Motility Tests for any indication 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.

## **MP261 Aqueous Drainage Shunt – REVISED – (clarified Description Language)**

**DESCRIPTION:** Aqueous drainage shunts are implantable devices that are intended to reduce intra-ocular pressure (IOP) in the anterior chamber of the eye in individuals with neovascular glaucoma or with glaucoma that has not responded to medical and conventional surgical treatments. Tube-shunt surgery is also frequently used to treat glaucoma when a person has:

- Failure of previous trabeculectomy.
- Neovascular glaucoma
- Corneal transplant

There are several devices that have been approved by the US Food and Drug Administration to facilitate the inflow/outflow balance of aqueous humor in the eye. Examples of devices that are FDA-approved for insertion by an external approach are Ex-PRESS™ Mini Glaucoma Shunt, **CyPass System**, iSTENT Trabecular Micro-Bypass, Baerveldt glaucoma drainage devices, Krupin eye valves, Molteno implants, and Ahmed Glaucoma Valve. The basic design of these devices is similar -- a silicone tube shunts aqueous humor from the anterior chamber to a fibrous capsule surrounding a synthetic plate or band positioned at the equatorial region of the globe. The capsule serves as a reservoir for aqueous drainage.

## MP272 PCA3 and Gene Expression Assays for Prostate Cancer – **RETIRED**

### MP273 Gene-based Testing and/or Protein Biomarkers for Diagnosis and Management of Prostate Cancer – **REVISED – (Title change; added clinical information)**

#### DESCRIPTION:

Prostate cancer antigen 3 (PCA3, also referred to as DD3) is a gene that expresses a non-coding RNA. PCA3 is only expressed in human prostate tissue, and the gene is highly overexpressed in prostate cancer. Because of its restricted expression profile, the PCA3 RNA is thought to be useful as a tumor marker. The PCA3 Assay is an automated molecular assay that helps physicians determine the need for repeat prostate biopsies in members who have had a previous negative biopsy.

In vitro gene expression prognostic assays measure gene expression in tumor tissue samples or from prostate biopsy samples to provide a personalized risk score indicative of a tumor's aggressiveness and may also provide a long-range prostate cancer -specific mortality risk score.

Epigenetic assays utilize methylation-specific PCR to assess DNA methylation of gene regions that are associated with prostate cancer. The test assesses the methylation status of glutathione s-transferase PI (GSTP1), adenomatous polyposis coli (APC), and RAS association (Ra)GDS/AF-6 domain family member 1 (RASSF1).

Prolaris® is a genomic test developed to aid physicians in predicting prostate cancer aggressiveness in conjunction with clinical parameters such as Gleason score and PSA. Prolaris® is a direct molecular measure of prostate cancer tumor biology. By measuring the expression levels of genes involved with cancer replication, Prolaris® is promoted as being able to more accurately predict disease progression.

Oncotype Dx® Prostate Cancer Assay (Genomic Health, Redwood City, CA) is a gene expression profiling test that uses archived tumor specimens as the mRNA source, and reverse transcriptase polymerase chain reaction (RT-PCR) amplification to quantify expression levels of 12 cancer-related and 5 reference genes to generate a Genomic Prostate Score. Decipher® is a 22 gene expression profile test intended to guide who can delay or defer radiation after radical prostatectomy. Promark™ is an automated quantitative imaging method to measure protein biomarkers by immunofluorescent staining in formalin-fixed paraffin-embedded biopsy tissue. It is designed to provide prognostic information to help differentiate patients to active surveillance or therapy.

The National Comprehensive Cancer Network® (NCCN) guidelines for prostate cancer (v 1.2018) encourages physicians to consider molecular testing of a patient's tumor post-biopsy when prostate cancer presents as low- or favorable intermediate-risk and life expectancy is greater than or equal to 10 years.

#### **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 patients 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  $\leq 6$  AND PSA  $\leq 10$  ng/mL AND  $<3$  prostate cores with tumor AND  $\leq 50\%$  cancer in any core AND PSA density of  $< 0.15$  ng/mL/g) OR
  - Low Risk Disease (T1-T2a AND Gleason Score  $\leq 6$  AND PSA  $\leq 10$  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.

### **MEDICARE BUSINESS SEGMENT:**

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

Gene expression prognostic assay (eg, Prolaris, ProMark, OncoType Dx) is covered for members to help determine which patients with early stage, needle biopsy proven prostate cancer can be conservatively managed rather than treated with definitive surgery or radiation therapy.

Palmetto GBA a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies and establishes the coverage policy for Medicare beneficiaries has determined that Prolaris testing will be considered for coverage 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. Patient Stage as defined by the one of the following:
  - Very Low Risk Disease (T1c AND Gleason Score  $\leq 6$  AND PSA  $\leq 10$  ng/mL AND  $<3$  prostate cores with tumor AND  $\leq 50\%$  cancer in any core AND PSA density of  $< 0.15$  ng/mL/g) **OR**
  - Low Risk Disease (T1-T2a AND Gleason Score  $\leq 6$  AND PSA  $\leq 10$  ng/mL), and
4. Patient has an estimated life expectancy of greater than or equal to 10 years, **and**
5. Patient 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, **and**
7. Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **and**
8. Test is ordered by a physician certified in the Myriad Prolaris™ Certification and Training Registry (CTR), **and**
9. Patient is monitored for disease progression according to established standard of care, **and**
10. Physician must report the development of metastasis or prostate cancer deaths in patients not treated definitively who were deemed low risk by the assay.

### **EXCLUSIONS:**

Unless coverage is mandated, the Plan considers **Decipher®** and **Promark™** **experimental, investigational, and unproven** for all indications including, but not limited to, the aid in predicting prostate cancer aggressiveness. 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.

The Geisinger Technology Assessment Committee determined that at the present time, there is insufficient evidence in the peer-reviewed, published medical literature to support the use of PCA3 assay to determine the need for repeat biopsy in members who have had a previous negative prostate biopsy. Unless mandated by state or federal regulation, this testing is currently considered to be **experimental, investigational or unproven**, and therefore **NOT COVERED**.

## **MP280 Whole Exome Sequencing – REVISED – (Added Indication)**

### **INDICATIONS: REQUIRES PRIOR AUTHORIZATION by a Plan Medical Director or Designee**

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
  - Developmental Pediatrician

**and**
2. The child (defined as under the age of 21) 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

**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 parents/legal guardians have been appropriately counseled about the testing by a qualified professional (same or similar to ordering providers) who is involved in the child's care

## **MP319 Percutaneous Left Atrial Appendage Occlusion – NEW POLICY**

**DESCRIPTION:** Percutaneous occlusion of a left atrial appendage (LAA) is a treatment strategy designed to prevent clots from originating in and traveling out of the LAA and potentially causing a stroke in adults with non-valvular atrial fibrillation.

**INDICATIONS:** Left atrial appendage occlusion using the Watchman device is considered medically necessary when the following criteria are met:

### **COMMERCIAL BUSINESS SEGMENTS**

- A diagnosis of non-valvular atrial fibrillation has been established; and
- Documentation of a CHADS<sub>2</sub> score of ≥ 2 or CHA<sub>2</sub>DS<sub>2</sub>-VASc score of ≥ 3; and
- The member is able to comply with short-term warfarin therapy; and
- Documentation of an appropriate rationale to support a non-pharmacologic alternative to warfarin due to the long-term risks of systemic anticoagulation clearly outweighing the risks of a percutaneous LAA closure device implantation

**MEDICAID BUSINESS SEGMENT: REQUIRES PRIOR AUTHORIZATION by a PLAN MEDICAL DIRECTOR or Desigee**

Coverage for left atrial appendage closure may be considered through the program exception process if the member meets the criteria outlined in this policy, and documentation that informed decision making leads to the conclusion that the long-term risks of systemic anticoagulation clearly outweigh the risks of a percutaneous LAA closure device implantation.

- A diagnosis of non-valvular atrial fibrillation has been established; and
- Documentation of a CHADS<sub>2</sub> score of ≥ 2 or CHA<sub>2</sub>DS<sub>2</sub>-VASc score of ≥ 3; and
- The member is able to comply with short-term warfarin therapy; and
- Documentation of an appropriate rationale to support a non-pharmacologic alternative to warfarin due to the long-term risks of systemic anticoagulation clearly outweighing the risks of a percutaneous LAA closure device implantation

**MEDICARE BUSINESS SEGMENT**

The Centers for Medicare & Medicaid Services covers percutaneous LAAC for non-valvular atrial fibrillation through Coverage with Evidence Development (CED). Please see: Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)

- Documentation of a CHADS<sub>2</sub> score of ≥ 2 or CHA<sub>2</sub>DS<sub>2</sub>-VASc score of ≥ 3; and
- The member is suitable for short-term warfarin therapy but deemed unable to take long-term oral anticoagulation; and
- Documented evidence of a formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation; and
- The member is enrolled in a prospective national registry; and
- Physician and facility requirements outlined in NCD20.34 are met

**ADDITIONAL INFORMATION**

CHADS <sub>2</sub>		CHA <sub>2</sub> DS <sub>2</sub> -VASc	
Risk Factors	Points	Risk Factors	Points
CHF	1	CHF/LVEF ≤ 40%	1
HTN	1	HTN	1
Age ≥ 75	1	Age ≥ 75	2
DM	1	DM	1
Stroke/TIA/Embolism	2	Stroke/TIA/Embolism	2
		Vascular disease (prior MI, PAD, or aortic plaque)	1
	Max 6	Age 65-74 years	1
		Sex category (female)	1
			Max 9

**EXCLUSIONS:**

The use of an FDA approved device for percutaneous left atrial appendage closure (eg, Watchman) for stroke prevention in members who do not meet the above criteria is considered experimental, investigational or unproven and **NOT COVERED**.

The use of other percutaneous left atrial appendage closure devices, including but not limited to the PLAATO, Cardioblate, Occlutech and Amplatzer devices, for stroke prevention in patients with atrial fibrillation is considered experimental, investigational or unproven and **NOT COVERED**.

## **MP320 Absorbable Hydrogel Spacer – NEW POLICY**

**DESCRIPTION:** The absorbable hydrogel spacer is designed to reduce unintentional rectal toxicity in men undergoing radiotherapy for treatment of prostate cancer. The hydrogel is administered using ultrasound guidance as a liquid that expands the space between the prostate and the rectal wall, where it solidifies into a soft, but firm, hydrogel within 10 seconds. The hydrogel remains in place for 3 months during prostate radiotherapy, after which it liquefies by hydrolysis, and is absorbed and cleared in the patient's urine.

### **INDICATIONS:**

Placement of an FDA-approved absorbable rectal hydrogel spacer (i.e. SpaceOAR) is considered medically necessary for the reduction of rectal and urinary toxicity in men with prostate cancer undergoing radiotherapy.

### **EXCLUSIONS:**

The use of absorbable hydrogel spacers outside of the indications listed in this policy are considered to be **experimental, investigational or unproven** and therefore, **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment for any other indication when compared to established tests 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.**

MP025 Transcatheter Closure Devices  
MP034 Foot Orthotics  
MP066 ESWT  
MP068 Reduction Mammoplasty  
MP078 Sexual Dysfunction Therapies  
MP090 Inj. Bulking Agents/Incontinence  
MP092 Imp. Cardiac Loop Recorder  
MP094 Unilateral Pallidotomy  
MP106 Ultrasound/ Pregnancy  
MP112 Wireless Capsule Endoscopy  
MP113 Electrical Stim Wound Healing  
MP158 Continuous Passive Motion  
MP172 MicroVas Vascular Treatment System  
MP176 Meniett Device  
MP179 Photodynamic Therapy for Esophageal and Lung Cancer  
MP189 Computer Aided Detection Technology  
MP196 Convection-Enhanced Drug Delivery  
MP209 Medical Error Never Events  
MP217 Polysomnography and Sleep Studies  
MP226 Proton Beam Radiation