"What's New" Medical Policy Updates March 2023

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of February that will become **effective April 15, 2023** (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within members 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.

MP010 Blepharoplasty – (Revised) – Added Criteria

Ectropion / Entropion Repair (67914-67917) (67921-67924)

Ectropion:

- Documentation of pain/discomfort or excessive tearing; and
- Kerato-conjunctivitis, keratitis or corneal ulcer

Entropion

- Documentation of inward-turned eyelid; and
- Irritation of the cornea or conjunctiva, pain/discomfort, excessive tearing, or trichiasis

MP029 Bone Growth Stim – (Revised) – Added Criteria

A Low-intensity non-invasive ultrasound stimulation is considered medically necessary for **ANY** of the following indications:

1. For the treatment of fresh, closed fractures with closed reduction in skeletally mature adults for **ANY** of the following acute fracture indications:
   a) Fresh (i.e. less than 7 days), closed, grade I open, tibial diaphyseal fractures; **OR**
   b) Fresh (i.e. less than 7 days), closed fractures of the distal radius (Colles' fracture)
   c) Fresh (i.e. less than 7 days), closed fractures at high risk for non-union due to position and poor vascular supply including but not limited to: carpal navicular/scaphoid fractures, Jones/5th metatarsal fracture, talar neck, tarsal navicular

MP265 Proteomic Serum Analysis – (Revised) – Added Exclusion; Revised Medicaid Status

DESCRIPTION:
OvaCheck®, developed by Correlogic Systems Inc, is a serum-based test that uses proteomics for the early detection of ovarian cancer. The test is based on proteomic patterns detected in the serum, which are then further analyzed with the use of a mass spectrometer to profile a population of proteins based on their size and electrical charge. This type of analysis contains thousands of data points, which undergo further computer analysis using artificial intelligence-based algorithms to identify a pattern that is consistent with ovarian cancer.

OVA1® (Vermillion, Inc) is a blood test to help assess the likelihood an ovarian mass is malignant prior to a planned surgery. In conjunction with clinical evaluation of members age 18 and older who have an ovarian mass and planned surgery, OVA1 may help triage according to probability of malignancy. OVA1® measures the levels of five proteins found in the blood and then uses a proprietary software to calculate a

single score. Risk is measured using a 0-10 scale versus predetermined cut-off points. Members who are pre-menopausal have a cut off of 5.0 whereas postmenopausal members have a 4.4 cutoff.

VeriStrat (Biodesix Inc) test uses mass spectrometry and a proprietary algorithm to analyze pretreatment plasma or serum to predict the benefit of single-agent chemotherapy or EGFR Tyrosine Kinase Inhibitor treatment in patients with non-small cell lung cancer with an unknown or wild-type variant of EGFR, or to identify patients with particularly aggressive disease. The NCCN recommends that proteomic testing be conducted in patients with NSCLC and wild-type or unknown EGFR status, and that a "poor" assignment indicates that the patient should not be treated with erlotinib in the second-line setting

Xpresys Lung and BDX-XL2 (Xpresys Lung 2) are plasma-based proteomic screening tests that measures the relative amount of proteins associated with lung cancer using multiple reaction monitoring mass spectroscopy. The testing is proposed to aid in differentiating likely benign from likely malignant nodules.

REVEAL Lung Nodule Characterization is a plasma protein biomarker test proposed to aid in characterizing indeterminate pulmonary nodules (4-30 mm) in current smokers aged 25 years and older. Using immunoassay, microarray, and magnetic nanoparticle detection techniques, the REVEAL Lung Nodule Characterization score is presented on a scale from 0 to 100 with a single cut point at 50. The score is based on an algorithm using factors from the patient's history (smoking history, age, and nodule size), and the presence of three blood proteins associated with lung cancer (epidermal growth factor receptor [EGFR], prosurfactant protein B (ProSB), and tissue inhibitor of metalloproteinases 1 (TIMP1).

The IMMray PanCan-d test combines an 8-plex biomarker signature with CA19-9 in a proprietary algorithm to detect pancreatic ductal adenocarcinoma (PDAC) in serum samples. The biomarkers are a combination of immunoregulatory and tumor biomarkers.

INDICATIONS:

Commercial and Medicaid Business Segment:

SEE ALSO MP355 Plasma-based Proteomic Testing in the Management of Pulmonary Nodules

VeriStrat®

Proteomic testing (VeriStrat®) is considered medically necessary for members with advanced non-small cell lung cancer (NSCLC) when ALL of the following criteria are met:

- The test results will assist in informing whether to proceed with erlotinib (Tarceva®) therapy.
- The test results will assist in informing overall prognosis and treatment strategy

Medicare Business Segment:

In compliance with Novitas LCD L35396 the **OVA1** proteomic assay will be covered according to the FDA label. OVA1 is intended only for members, 18 years and older, who are already selected for surgery because of their pelvic mass. It is not intended for ovarian cancer screening or for a definitive diagnosis of ovarian cancer.

In compliance with Novitas LCD L35396 the **Risk of Ovarian Malignancy Algorithm (ROMA™)** serum test will be covered to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy at surgery. ROMA™ will be considered reasonable and necessary for women who meet the following FDA labeling criteria:

- Over age 18;
- Ovarian adnexal mass present for which surgery is planned; and,

- Not yet referred to an oncologist.

In compliance with Novitas LCD L35396 the **Veristrat** proteomic assay will be covered to predict the benefit of single-agent chemotherapy or EGFR Tyrosine Kinase Inhibitor treatment in patients with non-small cell lung cancer with an unknown or wild-type variant of EGFR, or to identify patients with particularly aggressive disease.

MolDx has determined that **BDX-XL2** test will be covered for the management of a lung nodule, between 8 and 30mm in diameter, in patients 40 years or older and with a pre-test cancer risk (as assessed by the Mayo Clinic Model for Solitary Pulmonary Nodules) of 50% or less.

In compliance with Novitas LCD A58529 Response to Comments: Biomarkers for Oncology, **Cxbladder™ Detect, Cxbladder™ Monitor** will be covered when meeting the reasonable and necessary guidelines as outlined in Title XVIII of the Social Security Act, Section 1862(a)(1)(A).

EXCLUSIONS: All Business Segments Except as Annotated

PA Dept. of Human Services has determined OVA1 assay ~~is considered to be experimental/Investigational and therefore **NOT COVERED.**~~ may be considered on a per-case basis through the Program Exception process

Unless otherwise mandated (eg, Medicare), the Plan does **NOT** provide coverage for Proteomic Serum analysis to Identify Ovarian Cancer 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 test on health outcomes when compared to established tests or technologies.

Any use of VeriStrat® serum proteomic testing except as noted above is considered experimental/investigational or unproven and **NOT COVERED**.

Unless otherwise mandated (eg, Medicare), the Plan does **NOT** provide coverage for Proteomic Serum analysis to Identify Lung Cancer (Xpresys Lung, BDX-XL2, REVEAL Lung Nodule Characterization) 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 test on health outcomes when compared to established tests or technologies.

Unless coverage is mandated, the Plan does **NOT** provide coverage for Proteomic Serum analysis to bladder cancer (Cxbladder™ Detect, Cxbladder™ Monitor) 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 test on health outcomes when compared to established tests or technologies.

The Plan does **NOT** provide coverage for IMMray PanCan-d test 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 test on health outcomes when compared to established tests or technologies.

MP328 Genetic Susceptibility Cancer Panels – (Revised) – Revised Criteria and Medicare Coverage

INDICATIONS: <u>REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE</u>

For members presenting with a personal or family history of cancer suggestive of hereditary breast and ovarian cancer syndrome ~~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**

- HBOC related cancers include: breast, ovary, pancreas, and prostate

For members presenting with ~~clinical features and/or has a family history consistent with~~ a personal or family history of cancer suggestive of Lynch syndrome (LS), Familial Adenomatous Polyposis (FAP), MUTYH-associated polyposis (MAP), and rare polyposis syndrome such as Peutz-Jeghers or Juvenile Polyposis ~~syndrome hereditary cancer syndrome related to Lynch syndrome and Familial Adenomatous Polyposis~~, please refer to **MP098 Genetic Testing Related to Colorectal Cancer.**

- LS-related cancers include: brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal, small intestine, prostate, or ureter cancers, sebaceous adenomas, and sebaceous carcinomas.
- FAP, MAP, and rare polyposis syndromes are described in the above policy.

Genetic evaluation using a multi-gene cancer panel is considered medically necessary in members who have:

1. A personal or family history that is consistent with Hereditary Breast & Ovarian Cancer Syndrome (HBOC) *or* Lynch syndrome (LS), **AND**
   a) prior testing was limited (e.g. BRCA1 and BRCA2 sequencing only), or included high-penetrance genes only (e.g. *BRCA1, BRCA2, MLH1, MSH2, MSH6, PMS2, EPCAM, PTEN, STK11, TP53,*) and the result was negative or indeterminate; **AND**
   b) update testing is available with genes that have medical management recommendations per NCCN.

OR

2. A personal history of *any* solid tumor type, where more than one gene may be associated with an inherited cancer syndrome **AND** may be suggestive of more than one hereditary cancer syndromes where limited or targeted testing may miss actionable variant(s) (eg. Cowden Syndrome, Lynch syndrome, Hereditary Leukemia and Hematologic Malignancies Syndromes, Li-Fraumeni Syndrome, Von Hippel-Lindau disease, Multiple endocrine neoplasias, etc.) **OR**

3. 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 options; **and**
   - The member's personal and family history has been evaluated by a non-lab employed genetic counselor or a non-lab employed adequately trained health care professional, and the pedigree analysis is suggestive of an inherited susceptibility including **at least one of the following**:
     - A personal history of, or at least one first-degree blood relative with a history of, at least two different primary solid tumors at any age
     - A personal history of an HBOC-related cancer, or at least one first- or second-degree blood relative with a history of, an HBOC-related cancer at any age.
     - A personal history of an LS-related cancer and at least one first- or second-degree blood relative with an LS-related cancer at any age.
     - At least three people on the same side of the family with the same type of malignancy.
       - The member does not need to be affected, but a first-degree relative must have a combination of first, second, or third-degree blood relatives, on the same side of the family, diagnosed with any solid tumor or a hematologic malignancy of the same origin (e.g. myeloid vs lymphoid).

~~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 has been evaluated by a non-lab employed genetic counselor or a non-lab employed adequately trained health care professional, and the pedigree analysis 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~~**~~:~~
  - ~~A personal history of at least two different cancers~~
  - ~~~~
  - ~~A personal history of a cancer diagnosed at age 40 or younger~~
  - ~~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)~~
  - ~~At least one first, second, or third-degree blood relative diagnosed with breast, ovarian, prostate or pancreatic cancer at age 40 or younger~~
  - ~~At least three first, second, or third-degree blood relative on the same side of the family diagnosed with any cancer~~

Genetic testing is appropriate only when offered in a setting where a licensed or certified genetic counselor* or adequately trained health care professional is able to provide appropriate pre- ~~**and**~~ **or post-test genetic counseling, and medical necessity is supported by ALL of the following criteria:**

1. The information is needed to adequately assess risk in the member; **and**
2. The information will be used in the immediate care plan of the member; **and**
3. Pedigree analysis establishes that the insured individual is in a high-risk group for the disease; **or**
4. Clinical presentation of symptomology is evident and diagnosis cannot be established with conventional evaluation testing.

*A genetic counselor is considered by the Plan to be qualified if the following are met:

- M.S. or Ph.D. degree from a genetic counseling program approved/ certified by the American Board of Genetic Counseling or the American Board of Medical Genetics

or

- Board certified or board qualified/eligible in the orderly process of obtaining board certification by the American Board of Genetic Counseling or American Board of Medical Genetics

and

- Proof of current competence and demonstrated ability (minimum of two years recent and continual experience within the past three years).

EXCLUSIONS: Multi-gene hereditary cancer panels (including, but not limited to MI CancerSeek, etc) are unproven and not medically necessary for general population screening, and all other indications not meeting the criteria outlined in this policy.

Medicare Business Segment:

Germline testing for inherited cancer syndromes are covered per MolDx L38972

MP204 Nasal and Sinus Surgery – (Revised) – Added Exclusions

Ablation Therapy for Treatment of Allergic Rhinitis

The Plan does NOT provide coverage for the use of intranasal ablation of the posterior nasal nerves and/or sphenopalatine ganglion for the treatment of allergic and non-allergic rhinitis (e.g., by means of the Clarifix or RhinAer device) as it is considered to be unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

Radiofrequency Nasal Valve Remodeling

Low-dose radiofrequency intranasal tissue remodeling as a treatment of nasal airway obstruction is considered unproven and not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

MP209 Medical Error Never Events – (Revised) – Revised HAC List

Care Management Events:
• Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
• Patient death or serious disability associated with unsafe administration of blood products
• Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility
• Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
• Patient death or serious disability due to spinal manipulative therapy
• Patient death or serious disability associated with hypoglycemia, or manifestations of poor glycemic control, the onset of which occurs while the patient is being cared for in a healthcare facility
• Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
• Stage 3 or 4 pressure ulcers acquired after admission/ presentation to a healthcare setting
• Catheter-associated urinary tract infection
• Surgical site infection – mediastinitis after coronary artery bypass graft (CABG) surgery
• Surgical site infection – after total knee replacement
• Surgical Site Infection Following Certain Orthopedic Procedures • Spine • Neck • Shoulder • Elbow
• Surgical site infection – after laparoscopic gastric bypass or laparoscopic gastroenteroscopy
• Deep vein thrombosis/Pulmonary thrombosis
• Surgical Site Infection Following Bariatric Surgery for Obesity
• Surgical Site Infection Following Cardiac Implantable Electronic Device (CIED)

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.

MP184 Intracranial Percutaneous Transluminal Angioplasty
MP192 Intensity Modulated Radiation Therapy
MP207 Corneal Hysteresis
MP211 Endovascular Repair of Intracranial Aneurysms
MP220 Epiretinal Radiation Therapy
MP226 Proton Beam Radiation
MP236 Immune Cell Function Assay for Transplant Rejection
MP237 Transurethral Radiofrequency Tissue Remodeling
MP238 Ocular Blood Flow Tonometer
MP245 Helicobacter pylori Testing
MP248 SNP's To Predict Risk of Non-Familial Breast CA
MP252 Colon Motility Testing
MP254 Tinnitus Treatment
MP255 Comparative Genomic Hybridization or Chromosomal Microarray Analysis
MP275 Speech Generating Devices
MP281 Bone Morphogenetic Protein
MP282 Termination of Pregnancy
MP285 Tonsillectomy
MP286 Cholecystectomy
MP303 Genomic Analysis to Predict Thyroid Malignancy in FNA (Fine-Needle Aspiration)