“What’s New” Medical Policy Updates February 2023

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

MP075 Tissue Engineered Skin Substitutes – (Revised) – Clarified Coverage

For Dermagraft: The following limitation applies and will be considered NON-COVERED as being not medically necessary:

- Retreatment within 1 year following the last successful application
- Reapplication when initial application has resulted in no measurable response
- Retreatment of an ulcer following the unsuccessful treatment where it consisted of 8 failed Dermagraft® applications

Data regarding Permacol™ Biologic porcine mesh implant is limited to small case series, retrospective case reviews, and non-randomized comparison studies. There is minimal evidence in the peer-reviewed, medical literature of its effectiveness as an alternative to synthetic meshes, that it provides any advantage over other available surgical mesh, and information on the potential complications associated with its use is lacking. Requests for this product will be considered on a “per case” basis.

~~Due to limited studies, small study populations, variable outcomes and/ or poor study designs, there is insufficient evidence in the current published peer-reviewed medical literature to fully evaluate the clinical utility of any of the following products~~. The use of the following products or any FDA-approved product not listed is limited to the FDA approved indication.

MP230 Outpatient Pulmonary Rehabilitation – (Revised) – Added Indication

INDICATIONS:
Coverage for outpatient pulmonary rehabilitation will be approved up to 36 visits per benefit period. If coverage for pulmonary rehabilitation is available, the following conditions of coverage apply.

The Plan covers a comprehensive, individualized program of outpatient pulmonary rehabilitation as medically necessary for members with a documented diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD), either emphysema or chronic bronchitis, or other chronic pulmonary diseases that meet the following criteria. Pulmonary rehabilitation is considered *medically necessary* when **ALL** of the following exist:

- Activities of daily living (ADL) are currently limited by breathing difficulty
- Moderate to severe lung function impairment by pulmonary function tests: FEV1 at values 25-60% of prediction
- No other medical/psychological limitations (e.g. congestive heart failure, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke, dementia, organic brain syndrome)
- The members has stopped smoking for a minimum of 3 months (if applicable) prior to the requested therapy
- Stable on medical therapy (e.g. routine care under physician, compliance with medications and prescribed treatments)

Outpatient pulmonary rehabilitation as preoperative conditioning component for individuals that are candidates for lung volume reduction surgery or lung transplantation is considered *medically necessary.*

Pulmonary rehabilitation programs are considered medically necessary following lung transplantation.

MP365 Multi-Cancer Early Detection Testing – (NEW)

DESCRIPTION: Multi-Cancer Early Detection (MCED) tests are intended for use as cancer screening test in symptom-free individuals. MCED tests attempt to look for biological signals, or biomarkers, in blood that are released by cancer cells or induced by their presence to determine whether there is a strong likelihood that a person has cancer and identify where in the body that tumor is located. To date, these tests have evolving but limited data to show that they can detect multiple types of cancer. However, their sensitivity to find cancer when it is present varies by test and for each cancer type.

EXCLUSIONS: The Plan does **NOT** provide coverage for Multi-Cancer Early Detection Testing, including, but not limited to GRAIL Galleri, 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.

MP064 Breast Reconstruction Surgery – (Revised) – Added Clarification

DESCRIPTION:
Reconstructive breast surgery in men or women may be performed in connection with a mastectomy, lumpectomy, or breast trauma causing disfigurement to re-establish symmetry between the two breasts. The procedure includes reconstruction of the mastectomy site, creation of a new breast and creation of a new nipple/areolar complex. This may also include surgery and reconstruction of the unaffected breast to produce a symmetrical appearance. Breast reconstructive surgery following mastectomy may be performed at the time of the mastectomy or any time post-operatively.

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, or as a result of traumatic injury 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.

MP098 Genetic Testing/Colorectal CA – (Revised) – Revised Criteria

INDICATIONS:

***REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION**

- Genetic testing to determine the ~~carrier~~ status ~~of the adenosis~~ for clinical polyposis ~~coli (APC) gene~~ when criteria are met. (See applicable medical criteria below)
- ~~Genetic testing to determine the carrier status of the MutY homolog [MYH] when the member meets criteria (*See applicable medical criteria below)~~

- Lynch Syndrome - Genetic testing to determine the status of the mismatch repair associated genes when clinical evaluation criteria are met by personal or family history ~~Genetic testing to determine the carrier status of the HNPCC associated genes when either the Amsterdam or Bethesda criteria is met~~. (*See applicable medical criteria below)

MEDICAL CRITERIA:

Note: Germline MGPT should include at a minimum the following CRC risk-associated genes: APC, MUTYH, MLH1, MLH2, MSH6, PMS2, EPCAM, BMPR1A, SMAD4, PTEN STK11

POLYPOSIS SYNDROMES

APC & MUTYH gene testing for familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), and MutYH associated polyposis syndrome (MAP) is covered in ANY of the following situations:

1. >10 adenomatous colonic polyps in their lifetime; OR
2. A member has a close relative with a clinical or molecular diagnosis of FAP, aFAP, or MAP; OR
3. Personal history of desmoid tumor, hepatoblastoma, or cribriform-morular variant of papillary thyroid cancer

RARE POLYPOSIS SYNDROMES

1. >2 hamartomatous polyps in their lifetime; OR
2. >5 serrated colonic polyps in their lifetime

SMAD4 AND BMPR1A TESTING (Juvenile Polyposis Syndrome)

Genetic testing for SMAD4 and BMPR1A gene variants is considered medically necessary when any one of the following criteria is met:

1. A documented diagnosis of juvenile polyposis syndrome based on any one of the following:
   - at least 3 juvenile polyps in the colon; or
   - multiple juvenile polyps in other parts of the gastrointestinal tract; or
   - any juvenile polyps in a person with a known family history of juvenile polyps

   OR
2. Documentation of a close relative diagnosed with juvenile polyposis syndrome.

STK11 Testing (Peutz-Jeghers Syndrome)

Genetic testing for STK11 gene variants is considered medically necessary when any of the following criteria is met:

There is a known family history of STK11 (LKB1) gene mutation; or

The member has a clinical diagnosis of PJS based on as least TWO of the following features:

- Two or more histologically confirmed Peutz-Jeghers polyps of the small intestine
- characteristic mucocutaneous pigmentation of the mouth, lips, nose, eyes, genitalia, or fingers
- family history of Peutz-Jeghers syndrome

~~For APC gene testing for familial adenomatous polyposis (FAP) and Attenuated FAP (AFAP):~~

~~To determine carrier status of the adenomatous polyposis coli gene (APC) for familial adenomatous polyposis (FAP) or attenuated familial adenomatous polyposis (AFAP) in the following subjects:~~

1. ~~Individuals with greater than 10 adenomatous colonic polyps in their lifetime; OR~~
2. ~~In first-degree relatives (e.g., siblings, parents, offspring) of an individual diagnosed with FAP or AFAP; OR~~
3. ~~Personal history of desmoid tumor, hepatoblastoma, or cribriform-morular variant of papillary thyroid cancer~~

~~For MutY human homolog [MYH]) gene testing for MYH-associated polyposis (MAP) :~~

~~MYH-associated polyposis (MAP) genetic testing (gene MutY human homolog [MYH]) is covered in ANY of the following situations:~~

- ~~Confirmatory testing for individuals with a history of adenomatous polyposis (>10 adenomas) and negative APC mutation testing: **or**~~
- ~~For predictive testing when an individual has a first-degree relative with known MYH polyposis; **or**~~
- ~~For predictive testing when an individual has at least one first-degree relative affected with findings consistent with recessive inheritance (i.e., MAP)~~

Lynch Syndrome:

NOTE: LynchSyndrome genetic testing includes the following genes: MLH1, MSH2, MSH6, PMS2, EPCAM). Sequential testing is only cost effective when directed by dMMR status on a tumor. Otherwise, it is not a cost-effective approach for evaluation of hereditary colon cancer syndromes

~~For HNPCC; Lynch Syndrome genetic testing (gene MLH1, MSH2, MSH6, PMS2, EPCAM):~~

NOTE: COLARIS Test® is a patented test for assessment of colorectal cancer risk. It detects mutations in MLH1, MSH2 ,MSH6, PMS2, MYH and EPCAM genes. COLARIS AP detects mutations in the APC and MYH genes.

Lynch syndrome (LS): (MLH1, MSH2, MSH6, PMS2, EPCAM sequence analysis) gene testing is considered medically necessary for members who meet any one of the following criteria:
The member has:

- colorectal or endometrial cancer at <49, regardless of MSI status.
- colorectal or endometrial cancer >50 with known MMR deficiency (either high microsatellite instability [MSI] or loss of mismatch repair protein expression); OR

- is diagnosed with 2 or more Lynch Syndrome (LS)-associated tumors*, regardless of age; or
- a history of colon or endometrial cancer with a close relative with 2 or more LS-associated cancer, or one close relative with a LS-associated cancer <50y; OR
- has family history of a close relative** an molecular diagnosis of LS; OR
- has no personal history of cancer, but has:
  - ≥1 first-degree relative with a colorectal or endometrial cancer diagnosed <50 y
  - ≥1 first-degree relative with a colorectal or endometrial cancer and a synchronous or metachronous LS-related cancer regardless of age
  - ≥2 first-degree or second-degree relatives with LS-related cancers, including ≥1 diagnosed <50 y
  - ≥3 first-degree or second-degree relatives with LS-related cancers regardless of age
- has ≥5% risk of LS on a validated mutation prediction model (eg, MMRpro, PREMM1,2,5, MMRpredict);

~~Hereditary non-polyposis colorectal cancer (HNPCC)/Lynch syndrome (LS): (MLH1, MSH2, MSH6, PMS2, EPCAM sequence analysis) gene testing is considered medically necessary for members who meet any one of the following criteria:~~
~~The member:~~

- ~~is diagnosed with colorectal cancer with the MSI histology at any age; *or*~~
- ~~is diagnosed with endometrial cancer before age 50 years; *or*~~
- ~~meets Amsterdam or Revised Bethesda Guidelines; *or*~~
- ~~has a personal history of colorectal or endometrial cancer and the tumor shows evidence of mismatch repair deficiency (either high microsatellite instability [MSI] or loss of mismatch repair protein expression) at any age; or~~

- is diagnosed with a synchronous, or metachronous Lynch Syndrome (LS)-associated tumors*, regardless of age; or
- has a 1st- or 2nd-degree relative with a disease confirmed to be caused by a HNPCC mutation (genes MLH1, MSH2, MSH6, PMS2, EPCAM); or
- has ≥5% risk of LS on a validated mutation prediction model (eg, MMRpro, PREMM, MMRpredict)
    - http://premm.dfci.harvard.edu/
    - http://hnpccpredict.hgu.mrc.ac.uk/.
    - http://www4.utsouthwestern.edu/breasthealth/cagenc/.

* Lynch syndrome-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma as seen in Turcot syndrome), and small intestinal cancers, as well as sebaceous gland adenomas and keratoacanthomas (as seen in Muir-Torre syndrome).

** Close relative is considered by the health plan to be a first or second degree relative. Half and full relatives are counted.

Amsterdam II Criteria	Revised Bethesda Guidelines
Three or more relatives with a cancer associated with Lynch syndrome (cancer of the colorectum, endometrium, small bowel, ureter, or renal pelvis) and ALL of the following: • One must be a first-degree relative of the other two; AND • Two or more successive generations must be affected; AND • One or more relatives should be diagnosed before age 50 years; AND • Familial adenomatous polyposis (FAP) should be excluded in colorectal cancer (CRC) cases; AND • Tumors should be verified by pathologic examination.	Tumors from individuals should be tested for MSI in the following situations: • Colorectal cancer diagnosed in a patient who is less than 50 years of age. • Presence of synchronous, metachronous colorectal, or other LS-related tumors,* regardless of age. • Colorectal cancer with the MSI-H histology diagnosed in a patient who is less than 60 years of age. • Colorectal cancer diagnosed in one or more first-degree relatives with an LS-related tumor, with one of the cancers being diagnosed under age 50 years. • Colorectal cancer diagnosed in two or more first- or second-degree relatives with LS-related tumors, regardless of age.

* Lynch syndrome-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestinal cancers, as well as sebaceous gland adenomas and keratoacanthomas.

Immunohistochemical (IHC) Analysis for Mismatch Repair (MMR)

Universal MMR-IHC MSI testing performed on tissue from the primary tumor is considered medically necessary for all members with newly diagnosed colorectal cancer. Emerging data suggest metastatic tissue produces concordant results and should be considered an acceptable alternative.

Microsatellite instability (MSI) Testing

MSI testing is medically reasonable and necessary for members with an unresectable or metastatic colorectal primary, either MSI or a multigene NGS or other multi-analyte methodology panel inclusive of minimum 5-8 MSI microsatellite loci

~~Microsatellite instability (MSI) Testing or immunohistochemical (IHC) Analysis~~

~~Microsatellite instability (MSI) testing or immunohistochemical (IHC) analysis of the tumor is considered medically necessary when any of the following criteria are met:~~

- ~~all members with colorectal cancer regardless of age; or~~
- ~~members with endometrial cancer; or~~

~~For members with unresectable or metastatic solid tumors, either MSI or IHC or a multigene NGS or other multi-analyte methodology panel inclusive of MSI microsatellite loci, and MLH1, MSH2, MSH6 and PMS2 genes is medically reasonable and necessary.~~

~~MSI testing or IHC analysis should be used as an initial test in members with colorectal or endometrial cancer to identify those who should proceed with HNPCC mutation analysis.~~

~~*__NCCN Guidelines v1.2021 Lynch Syndrome__: the panel recommends tumor testing with IHC and/or MSI be used as the primary approach for pathology-lab-based universal screening. If tumor is available, LS-specific testing or multi-gene testing without IHC or MSI should be utilized in select cases under direction of a clinician with expertise in genetics, and should not be used as a universal screening strategy.~~

TUMOR GENOTYPING: KRAS, NRAS, BRAF

It is medically necessary for all members with newly diagnosed OR metastatic colorectal cancer to have tumor genotyping for RAS (KRAS and NRAS) and BRAF mutations individually via PCR or IHC, or as part of an NGS panel if individual testing is not available.

Related to Universal LS screening:
BRAF V600E is medically necessary when MLH1 OR MLH1/PMS2 are absent on MMR IHC studies to determine medical necessity for germline LS testing. MLH1 promotor hypermethylation testing is considered medically necessary after BRAF V600E testing has been completed and is negative, as the 3rd step in the algorithm to determine necessity for germline LS testing.

BRAF V600E testing is not indicated for use in endometrial cancers. MLH1 promotor hypermethylation should be performed ONLY if BRAF V600E is negative (absent).

~~BRAF V600E OR MLH1 PROMOTER METHYLATION~~

~~Genetic testing for BRAF V600E or MLH1 promoter methylation is considered medically necessary to rule out a diagnosis of Lynch syndrome when MLH1 protein is not expressed in a CRC tumor on immunohistochemical (IHC) analysis.~~

~~SMAD4 AND BMPR1A TESTING (Juvenile Polyposis Syndrome)~~

~~Genetic testing for SMAD4 and BMPR1A gene variants is considered medically necessary when any one of the following criteria is met:~~

1. ~~A documented diagnosis of juvenile polyposis syndrome based on any one of the following:~~
   - ~~at least 3 juvenile polyps in the colon; or~~
   - ~~multiple juvenile polyps in other parts of the gastrointestinal tract; or~~
   - ~~any juvenile polyps in a person with a known family history of juvenile polyps~~

   ~~**OR**~~
2. ~~Documentation of a relative diagnosed with juvenile polyposis syndrome.~~

~~STK11 Testing (Peutz-Jeghers Syndrome)~~

~~Genetic testing for STK11 gene variants is considered medically necessary when any of the following criteria is met:~~
~~There is a known family history of STK11 (LKB1) gene mutation; or~~
~~The member has a clinical diagnosis of PJS based on as least TWO of the following features:~~

- ~~Two or more histologically confirmed Peutz-Jeghers polyps of the small intestine~~
- ~~characteristic mucocutaneous pigmentation of the mouth, lips, nose, eyes, genitalia, or fingers~~
- ~~family history of Peutz-Jeghers syndrome~~

MP155 Cooling Devices – (Revised) – Clarified Medicare Coverage

MEDICARE BUSINESS SEGMENT

Cold therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met.
In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

A fluid circulating cold pad with pump (E0218) will be denied as not reasonable and necessary.

EXCLUSIONS: Unless mandated, there is insufficient evidence in the published, peer-reviewed medical literature to support that active or passive cooling devices when used to control swelling, edema, hematoma, hemarthrosis and pain provide any additional benefit over conventional ice packs. These devices are considered convenience items, and therefore are **NOT COVERED.**

MP350 Genetic and Biochemical Testing for Alzheimer's Disease and Dementia – (Revised) – Clarified Exclusions

EXCLUSIONS:
The Plan considers testing of genetic markers APOE, TREM2, APP, PSEN1, and/or PSEN2 for the diagnosis of Alzheimer's disease to be **experimental, investigational or unproven** and therefore **NOT COVERED** as a diagnostic technique for individuals with symptoms suggestive of Alzheimer's disease/ early-onset Alzheimer's disease(EOAD), or in asymptomatic individuals with a family history of Alzheimer's disease/ early onset Alzheimer's disease. There is insufficient evidence in the peer-reviewed medical literature to support testing for Alzheimer disease-related gene variants ~~biomarkers~~ improves health outcomes for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment.

MP367 Prescription Digital Therapeutics – (NEW)

DESCRIPTION: Prescription digital therapeutics (PDTs) are software applications that are prescribed by a licensed healthcare practitioner legally authorized to prescribe medications and devices. They are used on a mobile device such as a mobile phone, tablet, smartwatch, or laptop computer. The goal of prescription digital therapeutics is to evaluate, diagnose, manage symptoms, or treat an illness, injury, or disease.

MEDICAID BUSINESS SEGMENT

The PA DHS has determined that reSet, reSet-o, and Soryst may be considered for coverage under narrow clinical circumstances through the Program Exception process.
MCS-07-2022-003.pdf (pa.gov)

MCS-06-2021-005.pdf (pa.gov)

EXCLUSIONS:
Unless otherwise specified, the Plan does **NOT** provide coverage for Prescription Digital Therapeutics, including but not limited to Freespira, reSET, reSET-o, Insulia, BlueStar, NightWare, CanvasDx, Somryst, d-NAV System, EndeavorRX, and Parallel to evaluate, diagnose, manage symptoms, or treat an illness, injury, or disease because this technology considered **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 these digital applications on health outcomes 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.

MP055 Mastectomy for Gynecomastia
MP073 Deep Brain Stimulation
MP077 Noninv Mech tx for Back Pain
MP108 Work Hardening/Conditioning
MP123 HDR Temp Brachytherapy
MP191 Mindstreams Cognitive Health Assessment
MP205 Advanced Molecular Topographic Genotyping
MP210 Endometrial Ablation
MP224 Topical Oxygenation
MP308 Wireless Pulmonary Artery Pressure Monitoring
MP312 Routine Care in Clinical Trials
MP318 Spehnopalatine Gangloin Block for Headache

MP006 Nocturnal Enuresis Alarm
MP019 Laser Tx of Cutaneous Lesions
MP095 Craniosacral Therapy
MP099 Breast Implant Removal
MP119 Therapeutic Listening
MP126 Massage Therapy
MP130 Automated Amb. BP
MP138 Lysis Epidural Adhesions
MP142 Anodyne Infrared Therapy
MP149 Pulsed Electrical Stimulation for Osteoarthritis
MP169 Retinal Prosthesis
MP250 Bronchial Thermoplasty
MP262 Microarray Based Gene Expression Testing for Cancer of Unknown Origin
MP276 Hearing Aids
MP315 Esophageal Sphincter Augmentation
MP333 Coverage for Treatment of Rare Disease
MP352 Epidermal Nerve Fiber Density Testing