"What's New" Medical Policy Updates February 2025

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, 2025** (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.

MP073 Deep Brain Stimulation - Revised - Add Medicare Reference

FOR MEDICARE BUSINESS SEGMENT: See also NCD 160.24 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

EXCLUSIONS:

The Plan does **NOT** provide coverage for Deep brain stimulation for control of tremor induced by any diagnosis other than those listed above 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. The list of such diagnosis includes, but is not limited to:

- Trauma
- Neurological Degenerative Disorders
- Infectious Disease
- Obsessive Compulsive Disorder (must be reviewed by a Plan Behavioral Health Medical Director or designee)
- Tardive dyskinesia
- Cerebral palsy
- Chronic Intractable Cluster Headaches
- Post-traumatic tremor

- Multiple Sclerosis
- Metabolic Disorders
- Drug Induced Movement Disorders
- Tourette's Syndrome
- Neuropsychiatric conditions (must be reviewed by a Plan Behavioral Health Medical Director or designee)
- Chronic pain

MP075 Tissue Engineered Skin Substitutes - Revised - Add Medicare Cross Reference

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**.

MEDICARE BUSINESS SEGMENT: please also see Novitas Solutions, Inc. LCD L35041

MP077 Noniny Mech tx for Back Pain - Revised - Add Medicare Cross Reference

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, Biodex System 3, Cybex Back System)
- 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, AntalgicTrak, Ever-Trac ET-800, Dynatron 900, Integrity Spinal Care System, Rich-Mar Spina-Mobilizor,
 Triton ® DTS / Tru-Trac/ TX Traction System, Saunders Lumbar Home Traction
- Patient-operated spinal unloading devices (e.g. Orthotrac[™] Pneumatic Vest, Dr. Ho's Decompression Belt)

Medicare Business Segment: See NCD 160.16 Vertebral Axial Decompression (VAX-D)

MP098 Genetic Testing/Colorectal CA – Revised – Revise Criteria

Lynch Syndrome:

Lynch syndrome (LS): (*MLH1*, *MSH2*, *MSH6*, *PMS2*, *EPCAM*) gene sequencing with deletion and duplication analysis is considered medically necessary for members who meet any **one** of the following criteria OR meets current NCCN Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric criteria:

- Colorectal or endometrial cancer at ≤50, regardless of MMR or MSI status.
- Colorectal or endometrial cancer >50 AND
 - MMR deficiency per IHC analysis, OR
 - o MSI-high status in tumor tissue, OR
 - a pathogenic variant in a Lynch-related gene through next-gen sequencing in tumor tissue; OR
 - o **2** one or more close relatives with Lynch-related cancers diagnosed at any age.
- History of any solid tumor with evidence of mismatch repair deficiency (MMRd) or MSI-high status.
- Has been diagnosed with 2 or more Lynch Syndrome (LS)-associated tumors*, regardless of age;
- Has 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 no personal history of cancer, but has a family history of ANY of the following criteria:
 - o ≥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, regardless of age including ≥1 diagnosed <50 y</p>

 - Has family history of a close relative** with a molecular diagnosis of LS; OR
- Has ≥5% risk of LS on a validated mutation prediction model (eg, MMRpro, PREMM1,2,5, MMRpredict);

^{*} Lynch syndrome-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, ureter, bladder, and renal pelvis, biliary tract, brain, and small intestinal cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

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

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

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

OR

- 4. Colorectal cancer at any age with cumulative total of >5 adenomatous polyps OR
- 5. Two primary cancers with gastrointestinal or colorectal origin; OR
- 6. One or more upper GI polyps with the following histology: pyloric gland adenoma, gastric adenoma, or fundic gland polyps with high-grade dysplasia

MP168 Non-invasive Testing for Organ transplant Rejection – Revised – Add Prospera Coverage; Add Exclusion

Prospera Renal Transplant Testing (dd-cfDNA) is covered in the following scenarios:

- To assist in the evaluation of adequacy of immunosuppression in lieu of a tissue biopsy to make a management decision regarding immunosuppression, OR
- As a rule-out test for acute rejection in validated populations of patients with clinical suspicion of rejection to make a clinical decision regarding obtaining a biopsy, OR
- For further evaluation of allograft status for the probability of allograft rejection after a physician assessed pretest, OR
- To assess rejection status in members that have undergone biopsy, but the results are inconclusive or limited by insufficient tissue sampling

AlloSure Lung

Per LCD A58207 MolDX: Molecular Testing for Solid Organ Allograft Rejection which has jurisdiction for PA Medicare beneficieries, AlloSure Lung is a covered service.

Per LCD A58019 MolDx Molecular Testing for Solid Organ Allograft Rejection Prospera is a covered service for monitoring of Renal, heart or lung transplants.

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.

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 heart transplantation (e.g., myTAIHEART), 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.

Unless otherwise mandated, 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 lung transplantation, including but not limited to the detection of acute transplant rejection or transplant graft dysfunction 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.

The Plan does **NOT** provide coverage for the use of CXCL10 Urine Test because it is considered 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.

MP191 Mindstreams Cognitive Health Assessment – Revised – Revise Unproven Language

EXCLUSIONS:

The Plan does **NOT** provide coverage for Computerized Cognitive Health Assessment Systems, including but not limited to Mindstreams™, for use as a screening, evaluation and/or assessment tool as an alternative to traditional neuropsychological testing 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.

The Plan does **NOT** provide coverage for Computerized Cognitive Health Assessment testing for any indication including but not limited to sporting event field assessment of concussion or closed head injury 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.

MP205 Advanced Molecular Topographic Genotyping – Revised – Revise Unproven Language

EXCLUSIONS:

For the Medicare and Medicaid Business Segment, the Plan does NOT consider the use of advanced molecular topographic genotyping (including but not limited to Interspace Diagnostics Pathfinder TG®, PancraGEN®, PancraSeq®, BarreGEN®) medically necessary when used as a "first-line" pathology analysis.

Specific criteria of Non-coverage to include either:

- Image guided needle aspiration of the pancreatic cyst or cystic component of a mass lesion or dilated duct demonstrate definitive diagnosis of malignancy by cytology; OR
- Cytology not showing malignancy but meets AGA guidelines to reach a definitive diagnosis of benign disease. Lesions must be:
 - Under 1 cm;

- Lack a solid component;
- Lack concerning cytology features;
- Lack main pancreatic duct dilatation of > 1cm in diameter with absence of abrupt change in duct diameter;
- Have fluid CEA level not exceeding 5 ng/ml

FOR NON-MEDICARE BUSINESS SEGMENT:

The Plan does **NOT** provide coverage for advanced molecular topographic genotyping (including but not limited to RedPath Pathfinder TG, PancraGen™) because it is considered experimental, investigational er 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.

MP210 Endometrial Ablation – Revised – Revise Unproven Language

EXCLUSIONS:

There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of photodynamic ablation of the endometrium when compared to established technologies. It is considered experimental, investigational or unproven and is **NOT COVERED**.

There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of chemoablation of the endometrium when compared to established technologies. It is considered experimental, investigational or unproven and is **NOT COVERED**.

MP273 Gene-based Testing and/or Protein Biomarkers for Diagnosis and Management of Prostate Cancer – Revised – Add Coverage for MyProstateScore and IsoPSA

MyProstateScore (0403U) testing will be considered for coverage when all of the following criteria are met:

- The member is a candidate for initial or repeat prostate biopsy; and.
- The member does not have a diagnosis of prostate cancer.
 - o For men ≤ 75 years of age, PSA is ≥ 3 ng/mL AND/OR digital rectal exam findings are very suspicious for cancer.
 - o For men > 75 years of age, PSA is ≥ 4 ng/mL AND/OR digital rectal exam findings are very suspicious for cancer.

IsoPSA (0359U) testing will be considered for coverage when all of the following criteria are met:

- The member is a candidate for initial or repeat prostate biopsy; and.
- The member does not have a diagnosis of prostate cancer; and
- PSA is ≥ 3 ng/mL AND/OR digital rectal exam findings are very suspicious for cancer.

MP365 Multi-Cancer Early Detection Testing – Revised – Revise Unproven Language

EXCLUSIONS:

The Plan does **NOT** provide coverage for Multi-Cancer Early Detection (MCED) Testing, including, but not limited to GRAIL Galleri, OneTest™, Cancerguard™, 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 - Revised - Add Medicare Cross Reference

Removal of a Silicone Gel filled, Saline filled or "Alternative" implant is addressed in MP099 Breast Implants – Removal

Medicare Business Segment: see also NCD 140.2 Breast Reconstruction Following Mastectomy

MP099 Breast Implant Removal - Revised - Clarify Exclusion

EXCLUSIONS:

Removal of ruptured saline-filled breast implant in members who have undergone cosmetic breast augmentation (not related to breast cancer or prophylactic mastectomy) in the absence of complications (such as, but not limited to pain or contracture meeting Grade 3) to be is-considered cosmetic and NOT COVERED.

MP130 Automated Amb. BP - Revised - Add Medicare Cross Reference

Medicare Business Segment: see NCD20.19 Ambulatory Blood Pressure Monitoring

MP142 Anodyne Infrared Therapy - Revised - Add Medicare Cross Reference

Medicare Business Segment: see also CAG-00291N Infrared Therapy Devices

MP350 Genetic and Biochemical Testing for Alzheimer's Disease and Dementia – Revised – Add Coverage

INDICATIONS:

Germline testing via panel sequencing as a first line test is covered and considered medically necessary in the in members meeting the following clinical criteria:

- 1. Diagnosis of Amyotrophic Lateral Sclerosis (ALS) at any age, regardless of family history AND is considering therapy with Tofersen
- 2. Diagnosis of frontotemporal dementia at any age, regardless of family history, when necessary to aid in establishing a diagnosis.

Genoptying of APOE is covered and considered medically necessary ONLY in members meeting the following clinical criteria:

- 1. Clinical diagnosis of Alzheimer's disease AND
- 2. Required for eligibility to participate in clinical trial for anti-amyloid therapeutics

Genetic testing for amyloid precursor protein (APP), presenilin-1 (PSEN1), or presenilin-2 (PSEN2) for members with mild cognitive impairment or mild Alzheimer's D dementia who are less than 50 years of age as a companion diagnostic test and are being considered for aducanumab (Aduhelm) or lecanemabirmb (Leqembi) therapy. **81406**

Cerebrospinal fluid testing for measurement of phosphorylated tau (P-tau) protein and long form amyloid beta (also referred to as Aβ, Aβ1-42, Beta-amyloid [1-42], and Abeta42) is considered medically necessary in individuals when AD is suspected and for whom treatment with amyloid beta targeting therapy is being considered. **0346U**, **0358U**, **0445U**, **0459U**

EXCLUSIONS:

The Plan considers testing of genetic markers APOE, TREM2, APP, PSEN1, and/or PSEN2 for the diagnosis of Alzheimer's disease not meeting the criteria listed above to be experimental, investigational or unproven and therefore NOT COVERED as a diagnostic technique for individuals in:

- symptoms suggestive of Alzheimer's disease/ early-onset Alzheimer's disease(EOAD), or
- 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 APOE genotyping OR panel testing for Alzheimer disease-related gene variants. There is not sufficient data to support that this testing improves health outcomes or providers meaningful therapeutic opportunities for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment unless otherwise specified in this policy.

The Plan considers measurements of serum, urinary, CSF or skin fibroblast biochemical markers (including but not limited to tau protein, AB-42, neural thread protein) to be experimental, investigational or unproven and therefore NOT COVERED as a diagnostic technique for individuals with symptoms suggestive of Alzheimer's disease. There is insufficient evidence in the peer-reviewed medical literature to support testing for Alzheimer disease-related biomarkers improves health outcomes for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment.

0206U, 0207U

The Plan considers genetic testing or measurements of biochemical markers as a screening technique in asymptomatic individuals with or without a family history of Alzheimer's disease to be **experimental**, **investigational or unproven** and therefore **NOT COVERED**. There is insufficient evidence in the peer-reviewed medical literature to support testing for Alzheimer disease-related biomarkers improves health outcomes for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment.

0289U, 0412U

MP360 Minimal Residual Disease NGS Testing - Revised - Add Indications

DESCRIPTION:

Minimal Residual Disease (MRD) refers to a subclinical measure of cancer burden that remains during and following treatment. MRD status is a reliable indicator of clinical outcome and response to therapy such as drug resistance. and Results can be used for risk stratification and to guide treatment options when used in conjunction with other clinical and molecular data in acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), and multiple myeloma (MM). multiple malignancy types. MRD detection can identify patients at risk of recurrence earlier and is a practical addition to disease monitoring, following intervention.

MRD testing is recommended at a regular intervals over a specific time period. MRD testing often requires two types of assays to be performed as part of the service. First, a sample is taken from tumor diagnostic material to establish a baseline (solid and/or liquid) tumor signature as defined by the test methodology. This is followed by a series of assays run on a minimally invasive specimen (i.e., liquid biopsy or bone marrow aspirate) to detect the presence or recurrence of tumor based on the measured biomarkers, expression, or other analytes over various timepoints. This series of assays comprises a single test when the patient is known to have cancer.

Signatera (Natera) 0340U is a personalized molecular residual disease assay (MRD) using circulating tumor DNA (ctDNA), custom designed for each patient to help identify relapse of disease. The

Signatera test is personalized and tumor-informed, tailored to fit the unique signature of clonal mutations found in that individual's tumor. Signatera is offered for bladder, breast, colorectal, lung, melanoma, ovarian, and malignancies of unknown origin. This test can be performed as a standalone test, or as a tumor-informed test.

INDICATIONS:

Colorectal Cancer:

• Stage II-IV and oligometastatic colorectal cancer (CRC) in the adjuvant and recurrence monitoring setting

Breast Cancer:

- Stage II-IV breast cancer in the neoadjuvant setting, regardless of subtype
- Stage IIb and higher breast cancer in the adjuvant and recurrence monitoring settings

Muscle invasive bladder cancer (MIBC):

in the adjuvant and recurrence monitoring settings

Ovarian / Fallopian Tube / Peritoneal Cancer:

Stage II-IV in the adjuvant and recurrence monitoring settings

Any Solid Tumor:

For monitoring of response to immune-checkpoint inhibitor (ICI) therapy

ClonoSeq 0364U

INDICATIONS:

MRD testing (e.g., clonoSEQ) is considered to be medically necessary when performed in members with:

Multiple myeloma:

- During surveillance after response to primary treatment
- After each treatment phase (e.g. after induction therapy, high-dose therapy/autologous stem-cell transplantation, consolidation, and maintenance)

Acute myeloid leukemia:

- At completion of initial induction therapy
- Prior to allogeneic transplantation
- Periodic retesting guided by the regimen used

Acute lymphoblastic leukemia:

- At completion of initial induction therapy
- Periodic retesting guided by the regimen used
- Serial monitoring in members with molecular relapse or persistent low-level disease burden

Chronic lymphocytic leukemia or small lymphocytic lymphoma

- After completion of treatment
- For consideration of therapy with lenalidomide for high-risk patients after first-line therapy

Guardant Reveal

INDICATIONS:

MRD testing (ctDNA Guardant Reveal) is a tissue-free test. It is considered to be medically necessary when performed in members with:

Breast Cancer

- Stage I, II, or III breast cancer
- Recurrence monitoring after curative-intent procedure

Colorectal Cancer

- Early-stage Stage II and III colorectal cancer
- Recurrence monitoring after curative-intent treatment procedure

Lung Cancer

Stage II and III lung cancer

This test is not yet validated in other tumor types.

For the Medicare and Medicaid Business Segments

Although there is no National Coverage Determination issued for this service, CMS directives may allow MRD Signatera ClonoSeq and/or Guardant Reveal testing to be considered for coverage when used to predict risk of recurrence risk in patients members with colon personal history of cancer where treatment intent is curative.

Effective 12/26/2021 Palmetto GBA established a formal coverage policy for all Medicare patients. This local carrier determination is applicable nationally. Please refer to policy numbers L38779 and A58376 on Centers for Medicare & Medicaid Services website. Coverage criteria under the policy have been met for (1) the diagnosis of disease progression, recurrence, or relapse for colon cancer and (2) monitoring of response to immune-checkpoint inhibitor therapy for any solid tumor.

MP367 Prescription Digital Therapeutics - Revised - Add Smart Ring Exclusion

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 is 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.

Direct to consumer non-prescription digital software applications (with the exception of FDA approved or cleared* mobile apps for contraception based on fertility awareness covered per state or federal mandates) used on a mobile device such as a mobile phone, tablet, smartwatch, smart rings (eg, Oura Ring) or laptop computer are considered to be not medically necessary and are NOT COVERED. 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.
*NOTE: Natural Cycles is currently the only FDA-cleared fertility app (A9293)

The Plan does **NOT** provide coverage for direct to consumer devices to monitor personal biometrics, including but not limited to smart rings (eg, the Oura Ring), smart watches, or the monthly fees associated with their use. These devices are considered to be **Unproven** and are **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these biometric collecting devices on health outcomes.

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

MP108 Work Hardening/Conditioning

MP123 HDR Temp Brachytherapy

MP201 Obstructive Sleep Apnea

MP224 Topical Oxygenation

MP230 Outpatient Pulmonary Rehabilitation

MP308 Wireless Pulmonary Artery Pressure Monitoring

MP312 Routine Care in Clinical Trials

MP318 Sphenopalatine Gangloin Block for Headache

MP006 Nocturnal Enuresis Alarm

MP019 Laser Tx of Cutaneous Lesions

MP095 Craniosacral Therapy

MP119 Therapeutic Listening

MP126 Massage Therapy

MP138 Lysis Epidural Adhesions

MP149 Pulsed Electrical Stimulation for Osteoarthritis

MP155 Cooling Devices

MP169 Retinal Prosthesis

MP217 Polysomnography and Sleep Studies

MP250 Bronchial Thermoplasty

MP276 Hearing Aids

MP315 Esophageal Sphincter Augmentation

MP333 Coverage for Treatment of Rare Disease

MP352 Epidermal Nerve Fiber Density Testing

MP379 Wound Imaging and Nonthermal Wound Therapy

MP381 Trigeminal Neuralgia