“What’s New” Medical Policy Updates February 2024

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, 2024** (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 – Update CMS Rules

For Medicare Business Segment

If medical necessity is documented for both an upper eyelid blepharoplasty (15822, 15823) and a blepharoptosis repair (67901-67908) on the same eyelid the bundles apply and only one procedure is reimbursed. The member has no financial liability for the bundled service and a waiver does not apply. When a noncovered cosmetic procedure is performed in the same operative session on the same eyelid as a covered surgical procedure, the benefit will be applied for the covered procedure only. A pre-service organizational determination ~~An Advance Beneficiary Notice of Non-coverage (ABN) or waiver~~ must be given to members to provide notification of financial liability for the cosmetic procedure and any items or services that Medicare never covers or for which Medicare is not likely to provide coverage.

Following CMS transmittal 3854 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3854CP.pdf), the bundle applies to the performance of a medically necessary upper eyelid blepharoplasty (15822, 15823) and a medically necessary blepharoptosis repair (67901 – 67908) in a single operative session. However, the bundles do not apply to cosmetic services performed in the same operative session with a medically necessary service. For example, the bundle does apply to a cosmetic blepharoplasty performed on the same eye lid as a medically necessary blepharoptosis repair. For cosmetic procedures provide a pre-service organizational determination ~~a waiver or ABN~~ to inform the patient of their financial liability.

MP075 Tissue Engineered Skin Substitutes – Revised – Added Product Restrictions

The use of the following products or any FDA-approved product not listed is limited to the FDA approved indication.

AlloDerm® RTM Ready to Use	Conexa™	Integra™ Matrix Wound	Repriza™
AlloMax™	CorMatrix®	IntéguPly™	Restore® Orthobiologic
AlloMend™	CRXa™	Jaloskin®	Seamguard®
Allopatch HD	CryoSkin®	LiquidGen™	SportMesh™
Alloskin™	Cuffpatch™	MariGen Omega3	SS Matrix™
Alloskin RT™	Cymetra	Matriderm®	Stimulen™ Collagen
AlloWrap®	DeNovo® NT Graft	Matristem®	StrataGraft®
AmnioCare®	Dermacell™	Matrix HD™	Strattice™
AmnioExcel™	Dermadapt™ Wound Dressing	MediHoney®	Suprathel®
AmnioFix™	DermaMatrix™	Medeor™	SurgiMend®

Amniomatrix™	DermaSpan™	Mediskin®	Surgisis® (including Surgisis® AFP™ Anal Fistula Plug, Surgisis® Gold™ Hernia Repair Grafts, and Surgisis™)
AmnioMTM™	DressSkin™	Memoderm™	Talymed™
AmnioShield®	Duraform™	Menaflex™	TenoGlide™
Aongen™ Collagen Matrix	Duragen® XS	Meso BioMatrix™	TenSIX™
Architect Extracellular Matrix™	Duragen™ Plus	Neoform Dermis™	TheraForm™ Standard/Sheet
ArthroFlex®	DuraMatrix™	NEOX® 100 Quick-Peel	TissueMend®
Atlas Wound Matrix	Durepair® Regeneration Matrix	NEOX® 1k Wound Matrix	TranzGraft®
Avance® Nerve Graft	Endobon® Xenograft Granules	NEOX® FLO NuCel™	Unite™
Avaulta Plus™	Endoform™	Neuragen®	Veritas® Collagen Matrix
AxoGuard® nerve connector	ENDURAgen™	NeuraWrap™	X-Repair
AxoGuard® nerve protector	Epicel®	Neuroflex™	XCM Biologic™
Biobrane®	EpiDex®	NeuroMatrix™	Xelma®
BioDDryFlex®	EpiFix™	NeuroMend™	XenMatrix™
Biodesign	Excellagen®	NuCel®	Xwrap™ (Hydro, DRY, and ECM)
BioDExCel™	EZ Derm™	NuShield®	TheraSkin®
BioDfactor™	FlexHD® **Required Program Exception for Medicaid**	Oasis™	Amniply
BioDfence®	FloGraft™	OrthADAPT™	Reguard
BioDOptix™	FortaDerm™ Wound Dressing	OsseoGuard®	Cortiva
BioFiber™	Gammagraft™	Ovation®	AllopatchHD **Required Program Exception for Medicaid**
Biovance®		Puraply	AmnioBand **Required Program Exception for Medicaid**
C-QUR™	GORE®Bio –A	Pelvicol®	Guardian **Required Program Exception for Medicaid**
Celaderm	Grafix® CORE	Pelvisoft®	
CellerateRX®	Grafix® PRIME	Peri-Guard® Repair Patch	
CelluTome™	GraftJacket™	Peri-Strips Dry®	
CLARIX™ 100 Quick-Peel	Graftjacket™ Xpress injectable	Permacol™	
CLARIX™ 1k	HA Absorbent Wound Dressing	PriMatrix®	
CLARIX™ FLO	Helicoll	Promogran™	

CollaFix™	hMatrix®	PTFE felt	
Collamend™	Hyalomatrix®	Puracol®	
CollaSorb™	Inforce®	Puros® Dermis	
CollaWound™	Integra® Dermal Regeneration	Repliform®	

FOR MEDICAID BUSINESS SEGMENT:
Epifix (Q4186), Grafix Core (Q4132) and Grafix Prime (Q4133) require a program exception to be considered for coverage

Amnioband (Q4151), Guardian (Q4151) FlexHD (Q4128) and Allopatch(Q4128) require a program exception to be considered for coverage

MP080 Outpatient Cardiac Rehabilitation and Intensive Cardiac Rehabilitation – Revised – Clarify ICR Coverage

Cardiac Rehabilitation

INDICATIONS: A cardiac rehabilitation program is medically necessary within 12 months of any of the following:

- Acute myocardial infarction
- Coronary bypass surgery
- Stable angina pectoris unresponsive to medical therapy which prevents the patient from functioning optimally to meet domestic or occupational needs
- Percutaneous Transluminal Coronary Angioplasty or coronary stenting
- Cardiac valve replacement/ repair
- Class III or IV congestive heart failure unresponsive to medical therapy
- Heart or heart-lung transplant

Outpatient cardiac rehab is limited to a maximum of 36 dates of service per event per calendar year. ~~when provided by a participating provider~~

Intensive Cardiac Rehabilitation

- Intensive Cardiac Rehabilitation (ICR) sessions are limited to 72 one-hour sessions, up to 6 sessions per day for up to 18 weeks.

Medicare and Medicaid Business Segments ~~Only~~:

eCFR :: 42 CFR 410.49 -- Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

- In addition to the conditions listed in the Indications section, cardiac rehabilitation is also covered for stable chronic heart failure.
- Intensive Cardiac Rehabilitation (ICR) sessions are limited to 72 one-hour sessions, up to 6 sessions per day for up to 18 weeks.
- The following programs have received approval from Medicare as a component of ICR:
  - The Ornish Program for Reversing Heart Disease
  - The Pritikin Program
  - The Benson-Henry Institute Cardiac Wellness Program
- ~~The Centers for Medicare and Medicaid Services (CMS) has determined that the Ornish Program for Reversing Heart Disease meets the intensive cardiac rehabilitation (ICR) program requirements~~.

- Additional indications may be considered when reviewed and approved by a Plan Medical Director

Medicaid Business Segment. Any services beyond 36 per calendar year would require Medical Director review and would be covered if medically necessary.

LIMITATIONS:
Cardiac Rehab and Intensive Cardiac Rehab are not considered interchangeable and members cannot be reassigned mid-therapy cycle. Members must be assigned to one or the other upon submission of the requesting provider's order**.**

~~Outpatient cardiac rehab is limited to a maximum of 36 dates of service per calendar year when provided by a participating provider.~~

~~**Medicaid Business Segment**. Any services beyond 36 per calendar year would require Medical Director review and would be covered if medically necessary.~~

EXCLUSIONS:
Maintenance therapy, also known as Phase III cardiac rehab, is **NOT COVERED**.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

~~There is insufficient published peer reviewed medical literature to support the efficacy of the Ornish Cardiac Treatment Program. For all lines of business except Medicare and Medicaid, the Ornish Cardiac Treatment Program is considered **experimental, investigational or unproven.** The benefit for **Medicare and Medicaid** members will be in accordance to CMS mandated coverage as outlined in the current version of National Coverage Determination 20.10~~

MP098 Genetic Testing/Colorectal CA – Revised – Revised Criteria; Removed Prior Auth

DESCRIPTION:
Genetic testing related to colorectal cancer involves the analysis of DNA, RNA, chromosomes, proteins, and/or certain metabolites in order to detect heritable disease-related genotypes. This policy focuses primarily on testing for hereditary GI cancer risks. There are currently two well-defined categories ~~types~~ of hereditary colorectal cancer syndromes:, polyposis syndromes (includes familial adenomatous polyposis (FAP), MUTYH-associated polyposis (MAP), and other rare disorders) and hereditary nonpolyposis colorectal cancer syndrome, now called Lynch syndrome (LS)~~. (HNPCC).~~

Lynch syndrome accounts for approximately 3% of CRCs and 3% of endometrial cancers. APC-associated polyposis conditions historically accounted for about 0.5% of all CRC diagnoses; this figure is declining as more at-risk family members undergo successful treatment following early polyp detection and prophylactic colectomy.

Lynch Syndrome 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.

Multi-gene panel testing (MGPT) is now the preferred strategy for evaluation of inherited cancer risk. Compared to genetic evaluation based on family history or tumor testing for evidence of mismatch repair deficiency, multi-gene panel testing has comparable or even higher yield for identifying individuals with Lynch syndrome. There is a higher yield for identifying individuals with a pathogenic variant in a cancer

risk gene with known clinical actionability given shared phenotypes among hereditary cancer syndromes. Recent studies demonstrate a yield of 7.8% to 16.0% among patients with CRC diagnosed at any age.

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.

INDICATIONS:
The Plan considers molecular susceptibility testing for hereditary colorectal cancer via panel testing, medically necessary in ANY of the following indications:

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

- ~~Genetic testing to determine the status for clinical polyposis when criteria are met. (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 (*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~~

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:

- Colorectal or endometrial cancer at ≤50, regardless of MSI status.
- Colorectal or endometrial cancer >50 AND
  - MMR deficiency per IHC analysis, OR
  - MSI-high status in tumor tissue, OR
  - a pathogenic variant in a Lynch-related gene through next-gen sequencing in tumor tissue; OR
  - ≥2 close relatives with Lynch-related cancers diagnosed at any age.
- Has been diagnosed with 2 or more Lynch Syndrome (LS)-associated tumors*, regardless of age; or
- 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:
  - ≥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 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 MUT~~ut~~YH 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.

RARE POLYPOSIS SYNDROMES

1. >2 hamartomatous polyps in their lifetime; OR
2. >5 serrated colonic polyps in their lifetime; OR
3. >5 polyps of mixed histologic types <40y

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

POLE and POLD1 Testing (Polymerase proofreading-associated polyposis (PPAP))

Genetic sequencing and deletion/duplication analysis for POLE and POLD1 genes is considered medically necessary when any of the following criteria is met:

- ≥10 cumulative adenomas; AND
- Prior *APC* and *MUTYH* testing has been completed and is negative or inconclusive.

~~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~~

~~**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);~~

~~* 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.~~

Fecal DNA Testing: (e.g., Cologuard,) **DOES NOT REQUIRE PRIOR AUTHORIZATION** a noninvasive, multitarget fecal DNA test for the qualitative detection of colorectal neoplasia-associated DNA markers in addition to the presence of occult hemoglobin in stool is covered as a preventive screening methodology once every 3 years according to the following criteria:

- Age 45 to 85 years; and
- Asymptomatic (no signs/symptoms including but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test, or fecal immunochemical test); and
- There has been no documentation of a normal colonoscopy in the previous 10 years; and
- At average risk of developing CRC defined as:
  - no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease including Crohn's disease and ulcerative colitis; and
  - no family history of colorectal cancer, ~~or~~ adenomatous polyps, familial adenomatous polyposis (FAP / MAP), neurofibromatosis type 1, or Lynch syndrome,

  ~~, or hereditary nonpolyposis CRC~~

MP168 Non-invasive Testing for Organ Transplant Rejection – Revised – Added Medicare Coverage for AlloSure

LUNG TRANSPLANT TESTING

FOR MEDICARE BUSINESS SEGMENT:

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.

MP205 Advanced Molecular Topographic Genotyping – Revised – Specified Medicare Coverage, Exclusion Language

DESCRIPTION:
Advanced molecular topographic genotyping combines advanced molecular genetics with current pathology practices for a definitive diagnosis from existing specimens. These molecular tests are intended to be used adjunctively when a definitive pathologic diagnosis cannot be made due to inadequate tissue or indeterminate findings. The intention of this testing should be to inform appropriate surveillance or surgical strategies for each patient's unique diagnosis.

Several societies (AGA, ACG, ACR) have guidelines for monitoring of pancreatic cysts and indications for surgical resection, that are primarily based on expert consensus and radiologic features. The American Gastroenterological Association (Vege, et al., 2015) have no recommendations for use of topographic genotyping for evaluating pancreatic cysts. Other guidelines (NCCN, 2015; Vege, et al., 2015; Del Chiaro, et al., 2013; Sahani, et al., 2013; Tanaka, et al., 2012) have no firm recommendations for topographic genotyping for assessing indeterminate pancreatic cysts.

The current standard is to consider molecular studies to predict likelihood of malignant transformation. Cytology and CEA studies alone can increase cyst classification accuracy to 70% yet are noted to have inadequate sensitivity and specificity to diagnose advanced neoplasia. NGS studies of cyst fluid have improved accuracy in the diagnosis of cyst type (eg: cystadenomas do not require follow up) as well as risk classification of IPMN (intraductal papillary mucinous neoplasms). Early studies demonstrate that a combination of KRAS/GNAS gene variants with TP53, PIK3CA, and PTEN have 88% sensitivity and 97% specificity to diagnose IPMNs with advanced neoplasia (high-grade dysplasia or adenocarcinoma).

Interspace Diagnostics (formerly called RedPath) offers 2 tests that use the PathFinderTG® platform (PancraGEN® and BarreGEN®). PancreaSeq® is a similar test performed through UPMC Medical Laboratory.

Per the manufacturer: BarreGEN® is a molecular based assay that quantifies the mutational load (ML) in esophageal specimens obtained from patients who have BE. ML provides a measure of cumulative genomic instability (DNA damage). In looking at key genomic loci in patients with BE and assessing DNA damage in tumor suppressor genes associated with progression to HGD and esophageal cancer, the risk of more advanced disease can be determined ~~The results are thought to provide useful information for physicians to plan the best course of treatment for each patient's unique diagnosis~~.

FOR MEDICARE AND MEDICAID BUSINESS SEGMENT:

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

Consideration for coverage is limited to the Medicare Business Segment, in compliance with CMS directives.

~~The Plan considers the use of advanced molecular topographic genotyping (including but not limited to RedPath Pathfinder TG, PancraGen™) medically necessary for pancreatic cyst/mass when ALL of the following criteria are met:~~

Per the Medical intermediary, PathfinderTG® PancraGen™ ~~mass when ALL of the following criteria are met:~~

Per the Medical intermediary, PathfinderTG® PancraGen™ PancreaSeq® will be considered medically reasonable and necessary when selectively used as an occasional second-line diagnostic supplement:

- only where there remains clinical uncertainty as to either the current malignancy or the possible malignant potential of the pancreatic cyst based upon a comprehensive first-line evaluation; **AND**
- a decision regarding treatment (e.g. surgery) has NOT already been made based on existing information.

The specific requirements for medical necessity involve:

- Highly-concise affirmation, documented in the medical record, that a decision regarding treatment has not already been made and that the results of the molecular evaluation will assist in determining if more aggressive treatment than what is being considered is necessary.
- Previous first-line diagnostics, such as, but not restricted to, the following have demonstrated:
  - A pancreatic cyst fluid carcinoembryonic antigen (CEA), which is greater than or equal to 200 ng/ml, suggesting a mucinous cyst, but is not diagnostic.
  - Cyst cytopathologic or radiographic findings, which raise the index of malignancy suspicion, but where second-line molecular diagnostics is expected to be more compelling in the context of a surgical vs. non-surgical care plan.

~~▪ Documented evidence of an indeterminate diagnosis of malignancy remains after traditional pathologic and microscopic staining and analysis has been performed; AND~~

~~▪ The testing will result in a targeted, patient specific treatment plan with effective utilization of healthcare resources.~~

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 ~~RedPath~~ 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

MP312 Routine Care in Clinical Trials – Revised – Clarified Exclusions

EXCLUSIONS:

Costs which are not routine care costs, including, but not limited to, the following are excluded:

- The investigational item, device, drug or service (unless otherwise covered outside of the clinical trial);
  NOTE: For Medicare, Routine care items and services in CMS-approved Category A and B IDE studies are approved; however, the Category A devices are statutorily excluded, while Category B devices are reimbursable

MP365 Multi-Cancer Early Detection Testing – Revised – Added test name Exclusions

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.

MP019 Laser Tx of Cutaneous Lesions – Revised – Expanded Indications

For treatment of Port Wine Stains:

- The lesion results in bleeding or painful nodules.
- The patient is at risk for development of glaucoma (e.g., Sturge-Weber Syndrome, lesions that are located on the eyelids or the forehead)
- Port wine stain on the trunk or extremities associated with recurrent bleeding or painful nodules

For the treatment of any of the following conditions:

- Vascular hamartomas
- Kaposi's sarcoma
- Hereditary hemorrhagic telangiectasia
- Pyogenic granuloma
- Rosacea, severe refractory

And the lesion is affecting a vital structure (e.g., nose, eyes, ears, lips, or larynx) or results in any of the following:

- Pain
- Bleeding
- Ulceration
- Repeated infection
- Difficulty eating or swallowing

MP064 Breast Reconstruction – Revised – Clarified WHCRA Language

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

MP099 Breast Implant Removal – Revised – Consolidated Indications

INDICATIONS:

For members who have undergone cosmetic breast augmentation to treat gender dysphoria, or reconstruction following cancer surgery or prophylactic mastectomy, removal of breast implants is considered medically necessary for any of the following indications:

- Breast cancer (new onset or recurrent disease) or chest wall tumors in proximity to the implant; or
- Intra- or extra-capsular rupture of silicone gel implant; or
- Extra-capsular rupture of saline implant if post-cancer reconstruction cosmetic outcome is compromised
- Implants with severe contracture that interferes with mammography; or
- Implants with contracture associated with pain (Baker Class III or IV)*; or
- Implants complicated by persistent or recurrent local or systemic infection secondary to the breast implant and refractory to medical management, including antibiotics
- Erosion of the implant through the skin or scar
- Breast implant-associated anaplastic large cell lymphoma
- Elective removal in members at an increased risk of breast implant-associated anaplastic large cell lymphoma due to use of Allergan BIOCELL textured breast implants and tissue expanders
- Removal of ruptured silicone breast implant in members who have undergone cosmetic breast augmentation (not related to breast cancer or prophylactic mastectomy) is considered medically necessary based on increased risk of medical complications.

~~For members who have undergone reconstruction following a medically necessary mastectomy (due to malignancy or prophylactic mastectomy), removal of implants will be considered medically necessary for the following indications:~~

- ~~Breast cancer (recurrent disease) or chest wall tumors in proximity to the implant; or~~
- ~~Intra- or extra-capsular rupture of silicone gel implant; or~~
- ~~Implants with severe contracture that interferes with mammography; or~~
- ~~Extra-capsular rupture of saline implant if cosmetic outcome is compromised~~
- ~~Implants with contracture associated with pain (Baker Class III or IV)*; or~~
- ~~Implants complicated by persistent or recurrent local or systemic infection secondary to the breast implant and refractory to medical management, including antibiotics~~
- ~~Erosion of the implant through the skin or scar~~
- ~~Breast implant-associated anaplastic large cell lymphoma~~

MP217 Polysomnography and Sleep Studies – Revised – Revised Criteria

INDICATIONS:

UNATTENDED/UNSUPERVISED SLEEP STUDIES

I. The Plan considers the following portable or unattended sleep studies medically necessary as an alternative to in-laboratory polysomnography (PSG) for the diagnosis of OSA in members with a high pretest probability of moderate to severe OSA when no comorbidities exist that are contraindications to home/unattended testing:
    - A Type II or a Type III sleep testing device is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
    - A Type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility
    - A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

Contraindications to home/unattended testing (**ANY** of the following):

- Member is less than 18 years of age
- Suspected central sleep apnea or narcolepsy
- Moderate to severe heart failure (NYHA Class III or IV)
- Chronic pulmonary disease including moderate to severe asthma
- Established diagnosis of obesity hypoventilation syndrome
- Neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g. myasthenia gravis, amyotrophic lateral sclerosis (ALS), polymyositis, Guillian Barre syndrome, etc)
- Cerebral vascular accident (CVA) or transient ischemic attack (TIA) within the preceding 30 days;
- cardiac arrhythmias
- parasomnias that pose risk of injury
- General Screening of Asymptomatic patients

REPEAT UNATTENDED/UNSUPERVISED SLEEP STUDIES

The Plan considers repeat testing to be medically necessary for the following indications

- Evaluation of need for modification and/or discontinuance of positive pressure breathing devices if the member has experienced significant weight change or change in symptomology
- Evaluation of effectiveness of oral devices or surgical intervention

~~II. Polysomnography testing may be an eligible benefit when provided in a facility based sleep study laboratory which meets **ALL** of the following criteria:~~

~~a. The center is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder laboratories may be covered even in the absence of direct supervision by a physician when data is interpreted by a board certified sleep specialist or physician who fulfills eligibility criteria for the sleep medicine certification exam; **and**~~

~~b. The member is referred to the sleep center by a physician after a comprehensive sleep evaluation is completed, and the center maintains a record of the physician's orders and comprehensive sleep evaluation; **and**~~

~~c. The need for diagnostic testing is confirmed by medical evidence e.g. medical histories, examinations and laboratory tests; **and**~~

~~d. Scheduling of a follow-up visit with a physician to review results is standard.~~

SUPERVISED FACILITY- BASED POLYSOMNOGRAPHY

I. The Plan considers Type I polysomnography (PSG) when used to aid the diagnosis of obstructive sleep apnea (OSA) in members who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility be medically necessary for **ANY** of the following:

a. member does not meet criteria for unattended home sleep study
b. portable or unattended sleep study was technically inadequate or failed to establish a diagnosis of obstructive sleep apnea in spite of high pre-test probability
c. In the evaluation of sleep related behaviors that are violent or potentially injurious to the member or others
d. in members with neuromuscular disorders (e.g., myasthenia gravis, amyotrophic lateral sclerosis
e. (ALS), polymyositis, Guillian Barre syndrome, etc) and sleep related symptoms
f. evaluation of suspected narcolepsy or central sleep apnea

REPEAT FACILITY- BASED POLYSOMNOGRAPHY

The Plan considers repeat testing to be medically necessary for the following indications:

- Evaluation of need for modification and/or discontinuance of positive pressure breathing devices if the member has experienced significant weight change or change in symptomology
- Evaluation of effectiveness of oral devices or surgical intervention if the member does not meet criteria for an unattended home study

~~II. The Plan considers facility-based polysomnography medically necessary for **ANY** of the following:~~

~~a. The diagnosis of sleep related breathing disorders; or~~
~~b. To monitor the response to treatment or adjust treatment; or~~
~~c. In combination with multiple sleep latency testing in the evaluation of suspected narcolepsy; or~~
~~d. In the evaluation of sleep related behaviors that are violent or potentially injurious to the member or others; or~~
~~e. In certain atypical or unusual parasomnias; or~~
~~a. in members with neuromuscular disorders and sleep related symptoms; or~~
~~b. in members with comorbidities that may limit the accuracy of an unattended home study; or~~
~~c. portable or unattended sleep studies are technically inadequate to make a diagnosis of obstructive sleep apnea; or~~
~~d. to assist in the diagnosis of paroxysmal arousals or other sleep disruptions thought to be seizure related; or~~
~~e. in a presumed parasomnia or sleep related seizure disorder that does not respond to conventional therapy; or~~
~~j. when there is a strong indication of periodic limb disorder~~

~~III. Polysomnography for CPAP titration is medically necessary to evaluate the response to CPAP treatment in members who meet **EITHER** of the following criteria:~~

- ~~AHI greater than or equal to 15 events per hour; **or**~~
- ~~AHI greater than 5 and less than 15 events per hour with documented symptoms of daytime sleepiness, impaired cognition, documented hypertension, mood disorders, ischemic heart disease or history of stroke.~~

~~IV. Follow-up polysomnography or a cardiorespiratory sleep study is medically necessary in **ANY** of the following conditions:~~

~~a. To evaluate the response to treatment (CPAP, oral appliances or surgical intervention)~~
~~b. After substantial weight loss has occurred in patients on CPAP for treatment of sleep-related breathing disorders to ascertain whether CPAP is needed at the previously titrated level.~~
~~c. After substantial weight gain has occurred in patients previously treated successfully, who are, again, symptomatic despite continued use of the CPAP, to ascertain whether pressure adjustments are needed.~~
~~d. When clinical response is insufficient or when symptoms return despite initial response to treatment with CPAP~~
~~e. Significant change in cardio-respiratory status, such as the development or worsening of CHF or LV dysfunction.~~

V. A Multiple Sleep Latency Test (MSLT) may be considered medically necessary when documented evidence of excessive daytime somnolence exists despite the cessation of apnea or a significant decrease in AHI.

VI. Polysomnography followed by a MSLT performed the day after may be considered medically necessary in the evaluation of suspected narcolepsy or idiopathic hypersomnia if obstructive sleep apnea has been ruled out.

VII. Polysomnography may be considered medically necessary when a diagnosis of periodic limb movement disorder (PLMD) is being evaluated when all of the following criteria are met:

- A complaint of repetitive limb movement during sleep; AND
- other concurrent sleep disorders have been ruled out; AND
- At least one of the following is present:
  - Fragmented sleep; or
  - Difficulty maintaining sleep; or
  - Excessive daytime sleepiness

UNATTENDED/UNSUPERVISED SLEEP STUDIES

VIII. The Plan considers the use of portable or unattended sleep studies medically necessary in the following circumstances:

a. As an alternative to in-laboratory polysomnography (PSG) for the diagnosis of OSA in members with a high pretest probability of moderate to severe OSA when no comorbidities exist that are contraindications to home/unattended **testing (see exclusions); or**

b. When initiation of treatment is urgent and standard polysomnography is not readily available; or

c. To monitor the response to non-CPAP treatments for sleep apnea.

- And **all** of the following study criteria are met:

i. If the portable monitor records a minimum of airflow, respiratory effort and blood oxygenation; **and**

ii. The device allows for display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technician/technologist; **and**

iii. the data is interpreted by a board certified sleep specialist or physician who fulfills eligibility criteria for the sleep medicine certification exam; **and**

iv. The need for diagnostic testing is confirmed by medical evidence e.g. medical histories, examinations and laboratory tests; **and**

v. Scheduling of a follow-up visit with a physician to review results is standard.

LIMITATIONS:

* **For the Medicare & Medicaid Business Segment Only** - Additional coverage may be available through the applicable CMS mandates and/or the Coverage with Evidence Development (CED) when enrolled in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial.

The facility or provider must maintain documentation that it is in compliance with the criteria set by the American Sleep Disorders Association or the American Academy of Sleep Medicine. Failure to do so may result in a delay in processing of claims or denial of the claim.

The patient's medical record must contain documentation that fully supports the medical necessity and frequency for sleep studies as covered in the above policy. The documentation must include, but is not limited to, relevant medical history, physical examination and results of pertinent diagnostic tests and/or procedures.

Performance of home sleep testing is limited to FDA approved devices furnished with adequate patient instruction and support to assure successful completion and reliable results.

Home sleep testing should be performed over a period of three (3) consecutive nights to acquire quality data. The performance of home sleep testing for multiple nights will be considered as one (1) study.

EXCLUSIONS:

Polysomnography, cardiorespiratory sleep studies, and MSLT are **NOT COVERED** in the following situations:

a. For the diagnosis of chronic insomnia;

b. Preoperative evaluation for laser-assisted uvulopalatopharyngoplasty without clinical evidence of obstructive sleep apnea;
c. For the diagnosis of chronic lung disease;
d. For the diagnosis of typical, uncomplicated and non-injurious parasomnia when the diagnosis is clearly delineated;
e. Documented evidence of epilepsy with no specific complaints consistent with a sleep disorder;
f. Documented evidence suggestive of periodic limb movement disorder or restless leg syndrome unless symptoms are suspected of being related to a covered indication;
g. For the diagnosis of insomnia when related to depression;
h. For the diagnosis of circadian rhythm disorders.

The Plan considers the use of portable monitoring **NOT medically necessary** for patients who meet ANY of the following criteria:

i. The diagnosis of OSA in patients with significant co-morbid medical conditions that may degrade the accuracy of PM, including but not limited to
   i. Severe Pulmonary Disease
   ii. Neuromuscular Disease
   iii. Congestive Heart Failure

   iv. Diagnostic evaluation of OSA in patient suspected of having other sleep disorders, including but not limited to:
      1. Central Sleep Apnea
      2. Periodic limb movement Apnea
      3. Circadian rhythm disorders
      4. Narcolepsy
      5. General Screening of Asymptomatic patients
j. Diagnostic evaluation of patients suspected of having co-morbid sleep disorders
k. Diagnostic evaluation of patients with non-specific symptoms such as, but not limited to fatigue, malaise, etc., that may stem from other medical or psychological diagnoses.
l. General screening of asymptomatic populations

MP350 Genetic and Biochemical Testing for Alzheimer's Disease and Dementia – Revised – Expanded Description; Added Indications

DESCRIPTION:
Alzheimer disease is the most common cause of dementia. Alzheimer disease is a progressive, irreversible neurodegenerative disease. Individuals are typically classified into early-onset and late-onset disease using the age of 65 years as a cutoff. Genetic testing and biomarker testing has been proposed as a means to identifying a definitive diagnosis, improving understanding for the family, and allowing at-risk relatives to have predictive testing.

Genetic testing in the setting of neurological disorders lead to management changes primarily affecting the following areas of management: drug selection, drug repurposing, clinical trial eligibility, screening for non-neurologic comorbidities, and prognosis.

Studies of patients with early-onset Alzheimer's disease, both familial and apparently sporadic, have reported genetic testing yields of 5–13% when analyzing APP, PSEN1, and PSEN2. The clinical utility beyond familial risk remains unclear, and this testing is still not widely utilized. However, APOE genotyping has recently been used for dose stratification in experimental and emerging anti-amyloid therapeutics, and may impact prescribing decisions for lecanemab and other emerging amyloid-targeting agents.

Frontotemporal dementia (FTD) is an important cause of young-onset and non-autosomal dominant dementia. Three
genes account for the majority of genetic FTD: MAPT, GRN, and C9orf72, though many other genes have been implicated. In those with FTD-ALS and family history of either condition, up to 88% have a C9orf72 pathogenic RE. Variants in GRN account for about 5% of all FTD and 20% of FTD with positive family history.

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

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 in: ~~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 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.

MP360 Minimal Residual Disease NGS Testing – Revised – Added NavDx for Medicare

For the Medicare and Medicaid Business Segments

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

Coverage of ClonoSeq (baseline assay and multiple follow-up assays) is indicated for Acute lymphoblastic leukemia (ALL), Multiple myeloma (MM), and Chronic lymphocytic leukemia (CLL). Since Adaptive Biotechnologies is located in Seattle Washington, Noridian Healthcare Solutions, LLC policy A58997 applies.

NavDx Test

Per MolDx policy L38779, the NavDx test is considered to be medically necessary for the surveillance of recurrence in members with a personal history of documented HPV-driven oropharyngeal cancer, who

presently have no evidence of disease, starting three months following completion of any regimen of curative intent therapy, with a frequency of:

- not more often than every three months for the first 24 months thereafter,
- not more often than every six months for the next 36 months thereafter,
- not more often than annually thereafter until if and when a positive test result is detected.

MP367 Prescription Digital Therapeutics – Revised – Added Exclusion

MEDICAID BUSINESS SEGMENT

The PA DHS has determined that reSet, reSet-o, and Somyst may be considered for coverage under narrow clinical circumstances through the Program Exception process. **Note:** reSet and reSet-o may have limited availability or be unavailable due to manufacturing circumstances beyond the control of Geisinger Health Plan and/or the PA Dept. of Human Services.
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.

Direct to consumer non-prescription digital software applications used on a mobile device such as a mobile phone, tablet, smartwatch, 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.

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
MP210 Endometrial Ablation
MP224 Topical Oxygenation
MP230 Outpatient Pulmonary Rehabilitation
MP308 Wireless Pulmonary Artery Pressure Monitoring
MP318 Spehnopalatine Gangloin Block for Headache

MP006 Nocturnal Enuresis Alarm
MP095 Craniosacral Therapy

MP119 Therapeutic Listening
MP126 Massage Therapy
MP130 Automated Amb. BP
MP138 Lysis Epidural Adhesions
MP142 Anodyne Infrared Therapy
MP149 Pulsed Electrical Stimulation for Osteoarthritis
MP155 Cooling Devices
MP169 Retinal Prosthesis
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