Subject: Investigative & New Technology Assessment List (Non-Covered Services)

Medical Policy #: 36.0 **Original Effective Date:** 03-24-2021

Status: Review **Last Review Date:** 05-24-2023

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Presbyterian Health Plan (PHP) and Presbyterian Insurance Company (PIC) have a process to evaluate new technologies and/or new applications of existing technologies. PHP/PIC does not cover services or technology (i.e. medical devices and procedures, behavioral healthcare procedures and devices, or pharmaceuticals) that are considered experimental or investigational as safety and efficacy has not been supported based on published peer-reviewed medical and scientific literature.

The Technology Assessment Committee (TAC), comprised of appropriate medical and behavioral health professionals, is responsible for continually monitoring new technology developments and the new applications of current technology. As a result, the TAC takes on an advisory role for PHP/PIC and facilitates discussions of these new technologies. The TAC considers expert opinions, (i.e National Comprehensive Cancer Network), current medical literature including clinical trials, and governmental requirements and regulations in their review. The recommendations of the TAC are presented to the Clinical Quality/Utilization Management Committee (CQUMC) for review. PHP/PIC will not delegate authority to another entity for evaluation of any new technologies.

TAC reviews each technology or service through PHP Medical Directors, Technology Assessment Committee and utilizes an evidence-based approach using the following general criteria. The PHP Technology Assessment Committee reviews devices, procedures, and drugs at its discretion and will consider topics that are brought to the Committee by providers, practitioners, and/or device manufactures:

- Technology must have final approval from appropriate governing regulatory bodies
- Technology review by a published peer reviewed literature, or opinions and evaluations by national consensus panels, or other accredited bodies must permit conclusions on the effect of the technology on health outcomes
- Technology must improve health outcomes and the beneficial effects of the health outcomes must outweigh any harmful effects on health outcomes
- Technology must be equally beneficial as any established alternatives and should improve health outcomes as much as or more than any established alternatives, and must be cost-effective
- The technology must be attainable outside the investigational setting

In addition, the following research sources are considered throughout the review process:

- Hayes/Knowledge Center, a Division of TractManager
- Peer-reviewed scientific studies published in medical journals that meet nationally recognized requirements for scientific manuscripts
- Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's (NIH) National Library of Medicine
- Medical journals recognized by the Secretary of Health and Human Services
- Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, such as:
- Centers for Medicare and Medicaid Services (CMS), such as:
    - CMS National Coverage Determinations
    - Medicare Coverage Issues Manual
    - Local Coverage Determination, Medicare Carrier/Intermediary Policy Decisions
    - Medicare Decision Memos and Technology Assessments
    - National Comprehensive Cancer Network (NCCN)
    - Federal Agency for Healthcare Research and Quality
    - National Institutes of Health (NIH)
- The Presbyterian Health Plan Technology Assessment Committee may seek opinion from an outside source such as an Independent Review Organization.
- MCG Customized Guidelines®
- Other health insurance plans
- National boards recognized by the National Institutes of Health (NIH)
- Position and policy papers issued by professional organizations

- Peer reviewed, or scholarly articles written by persons who are expert in their field
- Medical Directories, such as Up-To-Date
- U.S. Food and Drug Administration (FDA).
- If a new service, including but not limited to services for behavioral health therapy, medical drug, or technology is not listed or determination on coverage has not been made, the service and technology will be considered experimental/investigational until it is evaluated by our medical directors or TAC.

In addition, the following listed procedures may contain those procedures that were not reviewed by TAC but are confirmed by the Knowledge Center/Hayes –that has rated the medication, treatment, procedure or device as being a "C" or "D" which indicates unproven benefit; not covered by Medicare (i.e. statutorily excluded) and all other peer reviewed literature deem the service to be investigation. Instead of maintaining separate policies the procedures are moved to this policy.

Experimental or investigational does not mean:

- Cancer chemotherapy or other types of therapy that are the subjects of ongoing Phase IV clinical trials.
- For Commercial plans - A drug provided to a patient during certain federally approved cancer clinical trials in New Mexico, if the drug has been approved by the FDA, whether or not the FDA has approved the drug for use in treating the patient's particular condition.

Coverage Determination

It is not an all-inclusive list of health care services considered investigative and therefore, not eligible for reimbursement. Always consult with enrollee's Certificate of Coverage (COC) or Summary Plan Description (SPD) as all eligible care is subject to limits and copayments specified by the Plan. To the extent, there is any inconsistency between a medical policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan documents will control. Note: CPT and HCPCS are listed for reference, only. The description of the health care service is the most definitive.

Last Reviewed by CQUMC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
05/20/2020	58674	**Acessa**, a radio frequency ablation for uterine fibroids is considered investigational and not covered for **Medicare, Commercial and Medicaid.**	Reviewed by TAC on 01/15/2020 and 10/19/2021. Use of radiofrequency ablation for uterine fibroids is consider experimental.
05/26/2021	22526, 22527	**Thermal Intradiscal Procedures (TIPs) (includes IDET & Nucleoplasty), (Percutaneous thermal intradiscal)** procedures to relieve low back pain is considered investigational, for **Medicare, Commercial and Medicaid.**	PHP follows MCG Criteria # A-0217 for Commercial; and CMS National Coverage Determination (NCD), for Thermal Intradiscal Procedures (TIPs) (NCD (NCD 150.11). Formerly MPM 20.7
11/18/2020	0404T	**Sonata**, a transcervical, intrauterine ultrasound-guided RFA for the treatment of uterine fibroids, considered investigational **for Medicare, Commercial and Medicaid.**	Reviewed by TAC on 10-21-20 and 10/19/2021. Use of transcervical, intrauterine ultrasound-guided RFA for the treatment of uterine fibroids known as Sonata is consider experimental.
05/26/2021	0335T, 0510T, 0511T, S2117	**Subtalar Arthroereisis** also referred to as extraosseous subtalar joint a surgical procedure option for a diagnosis of flexible flatfoot or flatfoot associated with generalized ligamentous laxity, such as subtalar instability, talipes equinovarus deformity (club foot), foot drop (dangle foot), and flatfoot deformity including congenital and adult-onset (acquired) flatfoot deformity (e.g., pes planus, pes planovalgus, pes valgus) and posterior tibial tendon dysfunction) or any other conditions because their clinical value has not been established therefore considered investigational for **Medicare, Commercial and Medicaid.**	Subtalar Arthroereisis and extraosseous subtalar joint as defined in Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, 290 Foot Care; and NMAC 8.310.2.12.H.(10).(b). Formerly MPM 19.6.
05/26/2021	43284, 43285	**LINX Reflux Management System** for the management of GERD, considered investigational and is not a covered	Reviewed by TAC Dec 2018. LINX Reflux Management System (a sphincter augmentation device) (Ethicon, Bridgewater, NJ)

Last Reviewed by CQUMC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
		benefit for **Medicare, Commercial and Medicaid.**	investigational for the management of GERD and all other indications. PHP follows MCG Criteria # A-0990, Implantable Magnetic Esophageal Ring (LINX). Formerly MPM 12.2.
05/26/2021	31660, 31661	**Bronchial Thermoplasty (BT) for treatment of Asthma**, is a bronchoscopic procedure that employs radiofrequency ablation to reduce the mass of airway smooth muscle (ASM), thus attenuating bronchoconstriction. Bronchial Thermoplasty for treatment of Asthma to be investigational and experimental and therefore is not a covered benefit for **Medicare, Commercial and Medicaid.** .	PHP follows MCG A-0634 Bronchial Thermoplasty. Due to contractual restrictions non-contracted providers may not access the MCG website but may obtain a copy of the criteria from the Prior Authorization staff. Formerly MPM 2.13
05/26/2021	** 46999	**Secca**® - is a minimally invasive outpatient procedure that uses radiofrequency energy delivered to the sphincter and anal canal to create thermal lesions for the treatment of fecal incontinence. Secca procedure is considered experimental and investigational therefore is not a covered benefit for **Medicare, Commercial and Medicaid.**	Transanal radiofrequency therapy for the treatment of fecal incontinence (also known as the Secca procedure) is considered investigational because its effectiveness has not been established. Formerly, MPM 19.8 ****** There is no specific CPT code for Secca. The following ICD-10: R15.0 thru R15.9 and F98.1 are non-covered.
05/26/2021	****** 64999	**Percutaneous neuromodulation therapy for the treatment of low back pain is investigational and is not a covered benefit for Medicare, Commercial and Medicaid** using a percutaneous electrode array BioWave is determined insufficient. There is no suffiecient evidence to support coverage of Biowave's Deepwave percutaneous neuromodulation pain therapy system at this time.	Percutaneous neuromodulation therapy for the **treatment of low back pain**. PHP follows CMS Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) (A56062) as well as Hayes. Formerly MPM 16.8 ******There is no specific **CPT®** code for PNT, code 64999 billed for percutaneous neuromodulation using a percutaneous electrode array (e.g., BioWave) is deemed a noncovered service.
11/18/2020	****** 64999	**Iovera cryonerve block** procedure is considered investigational and experimental and is not a covered benefit for **Medicare, Commercial and Medicaid.**	Reviewed by TAC on 10-21-20: iovera system is a portable cryogenic surgical device used to destroy tissue and/or produce lesions in nervous tissue creating a nerve block through application of extreme cold to the selected site. ****** There is no specific CPT code to report, when Cryotherapy, cryoablation, cryoanalgesia, cryoneuromodulation is performed, code 64999 should not be used.
11/18/2020	38232, 38240, 38241	**Stem Cell Therapy for Orthopedic Application:** - Autologous stem cell therapy for treatment of avascular necrosis of the hip is considered investigational and experimental and is not a covered benefit for **Medicare, Commercial and Medicaid.**	Reviewed by TAC on 10-21-20. Stem Cell Therapy - Autologous stem cell therapy for treatment of avascular necrosis of the hip involves deriving stem cells from a patient's own bone marrow or peripheral blood and transplanting them to the necrotic femoral head. Considered investigational for most payers for Mesenchymal stem cells.
11/17/2021	76641	The system device referred to as **Automated (Whole) Breast Ultrasound System (ABUS)** devices such as Invenia™ ABUS and Somo V® ABUS system (using CPT code 76641) are considered investigational, therefore, ABUS system is considered investigational and is not a covered benefit for **Medicare, Commercial and**	(ABUS) should not be used as a replacement for diagnostic mammography or diagnostic handheld ultrasound. Clinical evidence is inconclusive to show whether automated breast ultrasound improves the detection rate of breast cancer in comparison to screening mammography and handheld ultrasound.

Last Reviewed by CQUMC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
		Medicaid.	
05/26/2021	22869, 22870, C1821	**Interspinous Process Decompression (IPD) system** for treatment of lumbar spinal stenosis (LSS), is considered investigational and therefore is not a covered benefit for **Commercial, Medicaid and Medicare**.	PHP follows MCG A-0494, Spinal Distraction. devices, due to contractual restrictions, providers may not access the MCG website but can obtain a current copy of the criteria from the Prior Authorization Staff. Formerly MPM 25.0 Interspinous decompression devices and interlaminar stabilization devices include but are not limited to the following: • Aperius™ - PercLID™ System • Coflex® Interlaminar Stabilization Device • DIAM™ Spine Stabilization System • Falena® Interspinous Decompression Device • FLEXUS™ • Helifix® Interspinous Spacer System • In-Space • NL-Prow™ Interspinous Spacer System • Stenofixj. Superion® Interspinous Spacer System • Wallis® System • X-STOP® Interspinous Process Decompression (IPD®) System (discontinued in 2015) • X-STOP® PEEK (Polyetheretherketone) (withdrawn from market
05/26/2021	E0830, E0840, E0850,	**Intervertebral Differential Dynamics Therapy (IDD**) is a motorized traction device (computer controlled) spinal treatment used to stretch the space between the intervertebral space for internal disc Disruption. IDD therapy provides a program of treatments for relief from pain and disability for those patients suffering with low back pain. IDD therapy is considered experimental and investigational therefore is not a covered benefit **for Medicare, Medicaid and Commercial** members.	Vertebral decompression therapy is also referred to as mechanized spinal distraction therapy or IDD Therapy for the relief of symptomatic pain associated with lumbar disk problems. PHP follows CMS Local Coverage Determination (LCD L33823) and related article LCA (A52476). Formerly MPM 9.6
03/24/2021	C1839, 0617T, 0616T, 0618T	**CUSTOMFLEX Artificial Iris** for aniridia considered investigational for all LOB	Reviewed by TAC on April 17, 2019 to label Customflex artificial iris as investigational.
03/24/2021	0358T, 93702	**Bioimpedance Spectroscopy for the Assessment of Lymphedema**, is considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid.**	Bioimpedance spectroscopy has been proposed as a tool to detect early stage lymphedema. PHP follows MCG (A-0667), Bioimpedance Spectroscopy, the clinical indications current role remains uncertain. Due to contractual restrictions providers may not access the MCG website but may obtain a copy of the criteria from the Prior Authorization staff. Formerly *MPM 5.10*
11/17/2021	95012	**Nitric Oxide Breath Analysis for the Diagnosis of Asthma** considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid.**	Purpose of Technology: The measurement of nitric oxide (NO) concentration in expired breath has been introduced as an adjunct to or replacement for the established clinical and laboratory assessments for the diagnosis and/or management of asthma. PHP follows Hayes recommendation. Formerly MPM 5.5.
03/23/2022	81291	**MTHFR (5,10-methylenetetrahydrofolate reductase)** (eg, hereditary hypercoagulability) gene analysis,	PHP follows CMS, LCD (L36400)MolDX: Genetic Testing for Hypercoagulability Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR), Local Coverage Article (LCA A57571).

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		common variants (eg, 677T, 1298C) is not a covered benefit for **Medicare, Commercial or Medicaid** benefit.	PHP also follows MCG, Hyperhomocysteinemia, MTHFR Gene (A-0629). There is broad consensus in the medical literature that MTHFR genotyping has no clinical utility in any clinical scenario. Code 81291 was formerly listed in MPM 7.11.
03/23/2022	81422	**Fetal chromosomal microdeletion with cell-free DNA** (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood is considered investigational and is not a covered benefit for **Medicare, Commercial or Medicaid** benefit.	PHP follows ACOG: The use of cell free DNA (cfDNA) screening for fetal chromosomal copy number variants (microdeletions), have not been validated clinically and are not currently recommended (which includes both singleton or multiple gestation pregnancies).
07/27/2022	0379T	**ForeseeHome remote monitoring** is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration, as an aid in monitoring progression of disease factors causing metamorphopsia including but not limited to choroidal neovascularization (CNV). Foresee Home remote monitoring is considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid.**	Reviewed by TAC on 07/19/2022. PHP considers remote home monitoring with preferential hyperacuity perimetry (ForeseeHome device, Notal Vision Ltd.) experimental and investigational for detection of age-related macular degeneration (ARMD)-associated choroidal neovascularization and for all other indications.
03/22/2023	0089U	**Pigmented Lesion Assay (PLA)** by DermTech. Proprietary non-invasive adhesive patch biopsy genetic test. The test helps dermatologists rule out melanoma and the need for surgical biopsy of atypical, pigmented lesions, melanocytic in origin, with a suspicion for melanoma. **PLA** is considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid.**	Reviewed by TAC on 01-17-2023. PHP considers PLA experimental to rule out melanoma. The PLA is not intended to be used as a screening test in patients without melanocytic skin lesions. It is also not covered as an adjunctive test in lesions that are considered to already warrant a biopsy. The PLA is a decision tool for atypical melanocytic lesions prior to the decision to biopsy.
03/22/2023	K1018	**External upper limb stimulators tremor stimulator** of the peripheral nerves of the wrist, also referred to as transcutaneous afferent patterned stimulation, are wrist-worn noninvasive neuromodulation devices delivering peripheral nerve stimulation to the median and radial nerves to provide relief of hand tremors. Stimulation is calibrated according to the individual's tremor frequency. The device consists of a stimulator, wrist band and a magnetic charging base. The FDA approved external upper limb tremor stimulator for the treatment of essential tremor known as **Cala Trio** is considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid**.	PHP considers the product **Cala Trio Nerve Stimulation Device** by the manufacturer Cala Health, is considered experimental and investigational for the treatment of essential tremors because its effectiveness has not been established.
03/22/2023	K1024	The **Koya Dayspring System** is a wearable compression system for the treatment and management of lymphedema and is also indicated for the treatment of venous insufficiency	PHP considers the **Koya Dayspring System,** nonpneumatic compression system controller (with or without sequential calibrated gradient pressure) or garments are considered experimental and investigational for indication

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		and promotion of wound healing. The Koya Dayspring system consists of a segmental gradient compression device that provides comparable compression to existing pneumatic pumps via segments that contract and relax flexible frames in a segmental appliance without the use of air. Kova Dayspring system is considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid**.	such as and not limited to when used to promote wound healing; and treatment of lymphedema, and venous insufficiency because its effectiveness has not been established.
03/22/2023	0559T, +0560T, 0561T, +0562T	The **three-dimensional (3D) printing** technology is used to create 3D objects from plastic, metal, nylon or other source material by building the object layer upon successive layer until complete. The uses for **anatomic 3D printing** are actively being explored for multiple clinical applications and body systems including surgical planning and manufacturing of customized devices. The **anatomic 3D printing technology** is not a covered benefit for **Medicare, Commercial and Medicaid**.	PHP considers, the three dimensional (3D) printed anatomic models used to create 3D objects from plastic, metal, nylon or other source material are unproven and not medically necessary for all indications including but not limited to: preoperative surgical models for planning/rehearsal, tailored bone implants, prosthetic devices, operative templates/guides and bioprinting.
04/04/2023	64628, 64629	Thermal destruction (i.e., ablation) of the intraosseous BVN (Intracept ® Procedure) is a therapeutic, interventional surgical procedure used to treat cLBP of vertebrogenic origin. The procedure is performed using fluoroscopic imaging under moderate/conscious sedation or general anesthesia.	Reviewed by TAC on 04-04-2023. PHP considers the Trade/Device Name: Intracept Intraosseous Nerve Ablation System (RF Probe), Intracept Intraosseous Nerve Ablation System (Access Instruments), Relievant RF Generator are consider experiment when performed to treat Low Back Pain

Other related sources for non-covered services			
N/A	No specific codes.	No payment can be made under either the hospital insurance or supplementary medical insurance program for certain items and services, when the following conditions exist: • Not reasonable and necessary (§20); • No legal obligation to pay for or provide (§40); • Paid for by a governmental entity (§50); • Not provided within United States (§60); • Resulting from war (§70); • Personal comfort (§80); • Routine services and appliances (§90); • Custodial care (§110); • Cosmetic surgery (§120); • Charges by immediate relatives or members of household (§130); • Dental services (§140); • Paid or expected to be paid under workers' compensation (§150); • Non-physician services provided to a hospital inpatient that were not provided directly or arranged for by the hospital (§170); • Services Related to and Required as	Medicare does make payment under either the hospital insurance or supplementary medical insurance program for certain items and services, when the following conditions listed below exist. See the following sections of the Pub 100-02 - Medicare Benefit Policy Manual, Chapter 16 –General Exclusions from Coverage

		a Result of Services Which are not Covered Under Medicare (§180); • Excluded foot care services and supportive devices for feet (§30); or, • Excluded investigational devices (See Chapter 14)	
N/A	No specific codes.	See Medicare Coverage Related to Investigational Device Exemption (IDE) studies for those studies that have met CMS' standards for coverage. Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services.	For Approved IDE Studies see Medicare Coverage Related to Investigational Device Exemption (IDE) Studies, Approved IDE Studies

Reviewed by / Approval Signatures

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Date Approved: 05-24-2023

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    a) MCG Health Ambulatory Care 27th Edition, Breast Ultrasound, ACG: A-0101 (AC), last update: 02/01/2023. (breast [04/10/2023]
    b) United Healthcare, Breast Imaging for Screening and Diagnosing Center, Policy Number: Policy Number: 2022T0375BB Effective Date: April 1, 2023, (Computer-aided detection CAD Unproven). [Cited 04/10/2023]
    c) Humana, Breast Imaging, Policy Number: HUM-0374-023, Review Date: 08/25/2022. [Cited 04/11/2023]
    d) Hayes, Somo•V® Automated Breast Ultrasound System, ARCHIVED Dec 10, 2013, [04/10/2023]
11. **Interspinous Process Decompression (IPD) System**
    a) MCG Health Ambulatory 27th Edition, Spinal Distraction Devices, ACG: A-0494 (AC), Last Update: 02-01-2023. [Cited 04/10/2023]
    b) Hayes, X Stop Interspinous Process Decompression System (Medtronic Spine LLC) For Lumbar Spinal Stenosis, ARCHIVED Jan 25, 2016. [Cited 04/10/2023]
    c) CMS, Services That Are Not Reasonable and Necessary LCD (L35094) has been RETIRED, Date 07/01/2020.

[Cited 04/10/2023]

d) Hayes, Superion Interspinous Spacer System (Vertiflex) for Treatment of Neurogenic Claudication Caused by Spinal Stenosis, Sep 17, 2021. Accessed 04/11/2023
e) Aetna, Back Pain - Invasive Procedures, Effective: 07/31/1995, Next Review: 01/11/2024, Last review: 03-09-2023. [04-13-2023]
f) Cigna, Interspinous Process Spacer Devices, Policy Number: 0448, Effective Date 04/15/2022, Next review date: 04/15/2023. [04-13-2023]

12. **Intervertebral Differential Dynamics Therapy (for IDD® Therapy)**
    a) MCG, Traction, Spine, Ambulatory Care 27th Edition, ACG: A-0345, Last Update: 2/01/2023. [Cited 04/10/2023]
    b) CMS Local Coverage Determination (LCD L33823) Cervical Traction Devices, revision date: 01/01/2020, R7; related policy article (LCA A52476), revision date: 01/01/2020, R8. [Cited 04/13/2023]
    c) Aetna, Lumbar Traction Devices, Number: 0569, Effective: 11/09/2001, Next Review: 06/08/2023. [04-13-2023]
13. **Customflex**
    a) Hayes,CUSTOMFLEX ARTIFICIAL Iris (human Optics AG, Clinical Research Consultants Inc.) for Aniridia, Evolving Evidence Review, Clinical Research Response, Mar 10, 20222 [Cited 04/13/23]. (No relevant position statement)
    b) Aetna: Artificial Retina and Artificial Iris, Number: 0713, Last review: 10/12/2021, Next review: 08/10/2023. [Cited 04/13/2023
    c) Cigna: Prosthetic Devices, Policy# 0536, effective date 01/15/2022, Next review: 01/15/2024. [Cited 04/13/2023]
    d) Humana, Code Compendium, (Ophthalmology), Iris Prosthesis and Insertion, Policy Number : HUM-0571-007, Effective date: 06/23/2022, Date: 01/27/2022. [Cited 04/13/2023]
14. **Bioimpedance Spectroscopy for the Assessment of Lymphedema**
    a) MCG Health Ambulatory Care 27th Edition, Bioimpedance Spectroscopy, ACG: A-0667, last updated 2/01/2023. Accessed 04/13/2022
    b) Hayes, Bioelectrical Impedance (Bioimpedance) Analysis For Assessment of Lymphedema, Annual Review,Mar 17, 2023. [Cited 04/10/2023]
    c) CMS, Local Coverage Determination (LCD), Services That Are Not Reasonable and Necessary (L35094), RETIRED Revision Date: 07/01/2020, R43 and related LCA (A56967), RETIRED Revision date 07/01/2020, R4. [Cited 04/132023]
    d) Aetna – Lymphedema, Policy#0069, Effective 10/23/1995, Next review 01/11/2024. [Cited 04/13/2023]
    e) Cigna – Omnibus codes – Policy #0504, Effective date: 03/15/2023, Next review date: 03/15/2024. [Cited 04/13/2023]
    a)
    b)
15. **Exhaled Nitric Oxide Testing for Diagnosis and Management of Asthma**
    a) Hayes, Health Technology Assessment, Nitric Oxide Breath Analysis for the Diagnosis of Asthma, Annual Review: Feb 3, 2021, ARCHIVED Nov 06, 2021 [Cited 04/14/2023]
    b) Hayes, Health Technology Assessment, Nitric Oxide Breath Analysis for the Management of Asthma, Annual Review: Feb 2,2021, ARCHIVED Oct 29, 2021 [Cited 04/14/2023]
    c) CMS Novitas Pulmonary Function Testing (L35360) Revision Date 07/01/2020, R9, and related Article A57320, revision date: 10/01/2022, R6. (Note: LCD does not apply to exhaled NO) [Cited 04145/2023]
    d) Aetna, Exhaled Breath Test, Number 0691, Effective: 08/13/2004, Next review date 07/27/2023. [Cited 04/14/2023]
    e) Cigna, Exhaled Nitric Oxide in the Management of Respiratory Disorders, Policy Number: 0439, Next review date: 12/15/2023, [Cited 04/14/2023]
    f) Humana, Exhaled Breath Tests, Review Date: 04/28/2022, Policy Number: HCS-0325-015. (considered experimental and investigational). [Cited 04/14/2023]
16. **MTHFR (5,10-methylenetetrahydrofolate reductase)**
    a. CMS, (LCD): MolDX: Genetic Testing for Hypercoagulability Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36400), Revision date: 08/12/202111/01/2019, R#65. Related policy article A57571, revision date 08/12/2021, R1. [Cited 04/14/20233]
    b) ACOG Practice Bulletin, Inherited Thrombophilias in Pregnancy, Number 197, Replaces Practice Bulletin Number 138, September 2013, Reaffirmed 2022. [Cited 04/144-2023]
    c) MCG Health, Hyperhomocysteinemia, MTHFR Gene, ACG: A-0629, Ambulatory Care, 27th Edition. *Current Role Remains Uncertain.* [Cited 04/14/2023]
    d) Hayes MTHFR Genetic Testing In Common Clinical Conditions, Clinical Utility EvaluationAug 17, 2017, Annual Review: May 23, 2021 [Cited 04/14/2023]
17. **Fetal chromosomal microdeletion(s), with cell-free DNA**
    a) ACOG, Screening for fetal chromosomal abnormalities. ACOG Practice Bulletin No. 226. American College of Obstetricians and Gynecologists, (Replaces Practice Bulletin 163, May 2016, Reaffirmed 2018). [Cited 04/14/2023]
    b) UpToDate, Prenatal screening for common aneuploidies using cell-free DNA, Literature review current through: Mar 2023. | This topic last updated: Jan 11, 2023. [Cited 04/14/2023]
    c) MCG Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Microdeletion Syndromes, 27 Edition, ACG: A-0848, Last Update: 2/15/2023. [Cited 04/14/23]
18. **ForeseeHome remote monitoring**
    a) Clinical Trials Identifier: NCT01103505, HOme Vision Monitoring in AREDS2 for Progression to Neovascular AMD Using the ForeseeHome Device (AREDS), COMPLETED, Last Update Posted: 2019-07-30 [Cited 04/14/2023]
    b) Local Coverage Determination (LCD) for Services That Are Not Reasonable and Necessary (L35094), RETIRED July 2020. [Accessed 04/14/2023]
    c) Aetna Age-Related Macular Degeneration, policy number 0765, last review 10/26/2021, next review: 02/08/2024 [Cited 04/14/2023].

d) National Library of Medicine, Home Monitoring of Age-Related Macular Degeneration: Utility of the ForeseeHome Device for Detection of Neovascularization, 2021 Apr;5(4):348-356. doi: 10.1016/j.oret.2020.08.003, https://pubmed.ncbi.nlm.nih.gov/32810682/. [Cited 04/14/2023]

19. **Pigmented Lesion Assay (PLA)** by DermTech Operations, Inc
    a) CMS, LCD (L38178), MolDX Wisconsin, (New Mexico Part A), revision date: 12/30/2021, R1. Companion article LCA (A57983), Revision Date: 12/30/2021 R1. [Cited 04/14/2023]
    b) Hayes, Pigmented Lesion Assay (DermTech), Molecular Test Assessment, Sep 26, 2019, Annual review: Jun 14, 2022. [Cited 04/14/2023]
    c) MCG- Melanoma (Cutaneous) - Gene Expression Profiling - Ambulatory Care -27th Edition- Last Update: 2/1/2023. [Cited 04/14/2023]
    d) Aetna, Total Body Photography, Dermoscopy and Other Selected Noninvasive Dermatologic Tests, Number: 0188, Last review date: 02/11/2022. [Cited 04/14/2023]
    e) Cigna, Molecular Diagnostic Testing for Hematology and Oncology Indications, #0520, Next review date: 02/15/2023 [Cited 04/14/2023]
    f) Humana, Gene Expression Profiling, Reviewed date: 04/28/22, effective date: 03/23/2023, [Cited 04/14/2023]
20. **Cala Trio Nerve Stimulation Device, External Upper Limb Tremor Stimulator of the Peripheral Nerves of the Wrist**
    a) CMS, Medicare Benefit Policy Manual, Chapter 15, covered Medical and Other Health Services, 110.8 DMEPOS Benefit Category Determinations (Rev11769, Issued: 12-30-2022, Effective: 01-31-2023, Implementation: 01-31-23) [Cited 02-2-2023]
    b) Hayes, Cala Trio (Cala Health, Inc.) for Treatment of Essential Tremor, Feb 21., 2023. [Cited 02-23-2023]
    c) Pricing, Data Analysis and Coding (PDAC)-Medicare Contractor, DMECS, © 2023 PALMETTO GBA, LLC, VERSION: PROD-V37. [Cited 02-23-2023]
    d) Aetna, Functional Electrical Stimulation and Neuromuscular Electrical Stimulation, # 0677, Last review 11/01/2022, Next review: 07/21/2022 [Cited 02-23-2023]
    e) Humana, Code Compendium (Musculoskeletal and Neurologic), #HUM-0584-009, Effective Date: 06/23/2022 [Cited 02-23-2023]
21. **Koya Dayspring System, Nonpneumatic Compression Controller with Sequential Calibrated Gradient Pressure**
    a) CMS, Medicare Benefit Policy Manual, Chapter 15, covered Medical and Other Health Services, 110.8 DMEPOS Benefit Category Determinations (Rev11769, Issued: 12-30-2022, Effective: 01-31-2023, Implementation: 01-31-23) [Cited 02-2-2023]
    b) Pricing, Data Analysis and Coding (PDAC)-Medicare Contractor, DMECS, © 2023 PALMETTO GBA, LLC, VERSION: PROD-V37. [Cited 02-23-2023]
    c) Aetna Lymphedema, #0069, Last review 05/25/2022, Next review: 01/12/2023 [Cited 02/23/2023]
    d) Humana – Lymphedema, Policy Number: HUM-0432-030, Review Date: 03/24/2022 [Cited 02/23/2023]
22. **Anatomic Model 3D-printing**
    a) Hayes, Custom 3D Printed Prostheses for Temporomandibular Joint Disorders, Oct 27, 2022. [Cited 02-27-2023]
    b) Hayes, Custom 3D Printed Implants for Complex Lower Extremity Reconstruction, May 18, 2021. [Cited 02-27-2023]
    c) PMA database link Premarket Approval (PMA) (fda.gov) (enter "LZD" in product code) [Cited 03-03-2023]
    d) UHC, Omnibus Codes, Policy Number: 2022T0535MMM-Effective Date: October 1, 2022 ;Policy Number: ADMINISTRATIVE 212.61: [Cited 03-03-2023]
    e) Aetna Stereolithographic Models and Implants, Number 0613, Last review 08/08/2022, Next review date: 06-22-2023 [Cited 03-03-2023]
    f) CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 14- Medical Devices, Section 10, Coverage of Medical Devices. (Rev. 198, 11- 06-14). [Cited 03-03-2023]
    g) WPS, LCD L35490 Category III Codes, revision date: 06-12-2022, R30. [Cited 03-03-2023]
    h) CMS, Investigational Device Exemption (IDE) Studies, webpage last modified: 12/01/2021. [Cited 03-03-2023]
23. **Intracept System, a radiofrequency ablation (RFA) technology**
    a) LCD (L39420), Thermal Destruction of the Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Lower Back Pain, related article (A59205), Original Effective Date For services performed on or after 03/05/2023
    b) Hayes, Intracept Intraosseous Nerve Ablation System (Relievant Medsystems Inc.) for Treatment of Adults with Low Back Pain, Oct 24, 2022
    c) UpToDate, Subacute and chronic low back pain: Nonsurgical interventional treatment, Literature review current through: Feb 2023. | This topic last updated: Jun 10, 2021
    d) Aetna, Back Pain - Invasive Procedures, No. 0016, Last review: October 4, 2022, Next review: January 12, 2023
    e) Cigna, Minimally Invasive Spine Surgery, and TP injection, Effective date: July 15, 2022, next review July 15, 2023
    f) Human, Neuroablative Techniques for Chronic Pain, No. HCS-0387-022, Effective: Jan 27, 2022, Next review: not stated.
    g) UHC, Ablative Treatment, for spinal Pain, Effective: March 01, 2022, Next review: not stated

Publication History

03-24-21	New policy. This MPM consist of past and present procedures that were reviewed by Technology Assessment Committee (TAC) and concluded to be investigation and/or experimental; as well as those MPM(s) denoted to be an absolute investigative procedure that may have been retired. The intent is to list investigative procedures(s) that reside in separate MPMs and consolidate into one policy.
05-26-21	Policy updated for the following MPMs that were previously standalone policy as investigational and experimental. After migration of the policies to this MPM the policies will be retired:

MPM 2.13 Bronchial Thermoplasty For Treatment of Asthma - 31660,31661 will be configured to not pay for bronchial thermoplasty for Medicare, Commercial and Medicaid

MPM 9.6 Intervertebral Differential Dynamics Therapy- E0830, E0840, E0849, E0850, E0855 will be configured to not pay for Medicare, Commercial and Medicaid

MPM 12.2 LINX Reflux Managemnt System for Treatment of GERD - 43284, 43285 will be configured to not pay for Medicare, Commercial and Medicaid

MPM 16.8 Percutaneous Neuromodulation Therapy (PNT) - There is no specific code for percutaneous neuromodulation and the most appropriate code is (64999). Due to code being an unlisted code and could be used for other procedure in the nervous system, we are unable to configure.

MPM 19.6 Subtalar Arthroereisis Implant for Pediatric Patients - S2117,0335T, 0510T, & 0511T will be configured to not pay for Medicare, Commercial and Medicaid

MPM 19.8 Secca Procedure for Fecal Incontinence - 46999 will be set to not pay for ICD-10: R15.0 thru R15.9 and F98.1 for Medicare, Commercial and Medicaid

MPM 20.7 Thermal Intradiscal Procedures (IDET & Nucleoplasty) - 22526, 22527 to deny as investigational for all LOB

MPM 24.1 Whole Breast Ultrasound, Semi-Automatic - 76641, 76642 will be configured to not pay for Medicare, Commercial and Medicaid

MPM 25.0 Interspinous Process Decompression - 22869, 22870, C1821 will be configured to not pay for Medicare, Commercial and Medicaid

MPM 5.10 Bioimpedance Spectroscopy for the Assessment of Lymphedema, Codes 0358T and 93702 will be set to not pay for all LOB.

LADR (including revision) codes 22857, 22862, 22865 and add-on code 0163T, 0164T and 0165T are considered investigational for all LOB, will be configured to not pay.

12-20-2021 Update to include iris prosthesis procedure codes 0616T and 0618T, which will be configured to deny as experimental/investigational.

11-17-21 Policy updated. Reviewed by PHP Medical Policy Committee on 10/13/2021 to move MPM 5.5, Exhaled Nitric Oxide Testing for: Diagnosis and Management of Asthma to this policy then retire MPM 5.5. Before retirement of policy, Nitric Oxide Breath Analysis for the Diagnosis of Asthma was reviewed and is still considered investigational and is not a covered benefit for Medicare, Commercial and Medicaid. CPT code 95012 will remain configured to not pay for all product lines. Updated the language for Automated, Whole-Breast Ultrasound (ABUS) and included MCG A-0101 and LCD L33950. The decision to retire the MPM 24.1 has been rescinded (see the MPM for more details on configuration and coverage determination for codes 76641 and 76642). Acessa and Sonata were reviewed by TAC on 10/19/2021 and concluded these procedures are still considered experimental.

03-23-22 Policy updated. Reviewed by PHP Medical Policy Committee on 03-02-2022. There is broad consensus in the medical literature, MTHFR genotyping (Code 81291), has no clinical utility in any clinical scenario. This testing is considered investigational and is NOT covered for Medicare, Commercial or Medicaid. CfDNA test (code 81422) have not been validated clinically and are not currently recommended. Code 81291 configured as investigational. MTHFR and fetal chromosomal microdeletions with ctDNA were moved to this policy from MPM 7.11 and MPM 20.15. Correction to ACOG citation for Acessa, regarding the entire publication date was erroneously left out.

05-25-22 Annual review. Reviewed by Medical Policy Committee on 04-22-2022. Of the (19) listed investigative procedures the following have been updated:

- Title changed from “Subtalar Arthroereisis (SA) for Pediatric” to “Subtalar Arthroereisis” and the description of SA was updated.
- Title changed from “Stem Cell Therapy” to “Stem Cell for Orthopedic Application.”
- Reference changed for Intervertebral Differential Dynamics Therapy.
  - Now follow CGS LCD (L33823) and LCA (A52476).
  - Removed to follow NCD (160.16), Vertebral Axial Decompression.
  - Due to switching reference, codes E0849 and E0855 are now considered covered per LCD (L33823) and LCA (A52476).
  - Previous configuration to not pay for codes E0849 and E0855 will be removed.
  - Codes E0830, E0840 and E0850 will continue to be non-covered.
- Bioimpedance Spectroscopy for the Assessment of Lymphedema – the description has been updated.
  - Lumbar Artificial Disk Replacement (LADR), which includes revision.
  - Updated language to say we follow NCD 150.10 for “members over 60 years of age.”
  - Added (not New Mexico jurisdiction) reference: We will adopt Palmetto LCD (L37826) that states non-coverage of LADR for “members 60 years of age and younger.” Note: there is no New Mexico region LCD for LADR.

Policy updated 07-27-2022: Reviewed by TAC July 19, 2022, then by PHP Medical Policy Committee on 07/20/2022. ForeseeHome remote monitoring for detection of age-related macular degeneration (ARMD)-associated choroidal neovascularization and for all other indications are considered investigation for all

	LOB. Code 0379T will be configured as investigation for all LOB. **Policy updated 01-25-2023**: Reviewed by TAC Jan 17, 2023. The Technical Assessment Committee (TAC) have concluded the sole proprietary lab by DermTech for Pigmented Lesion Assay (PLA) by DermTech, for melanoma test, code (0089U) has been determined investigation for all lines of business. The PHP Medical Policy Committee reviewed the decision and has agreed PLA is determined investigation on 01-18-2023 and to configure code 0089U as investigational for ALOB. On 03-24-2021 code 81291 was set to deny as investigational for ALOB. **Policy updated 03-22-2023**: Reviewed by PHP Medical Policy Committee on 02-24-2023. Code K1018 and K1024 were announced in CMS, Medicare Benefit Policy Manual, Ch.15, 110.8 DMEPOS Benefit Category Determination for Part B. Codes will be set as investigational for ALOB. For ALOB, the 3D printing of anatomic structures for pre-operative planning and other applications experimental and investigational because of insufficient evidence of its effectiveness. Codes 0559T, 0560T, 0561T, 0562T will be config as investigational for ALOB.
05-24-2023	Annual review. Reviewed by Medical Policy Committee on 04/14/2023. Lumbar Artificial Disc Replacement (codes 22857, 22862, 22865, 22860, 0164T, and 0165T) was removed from the policy then moved the item to a new policy, see MPM 56.0. The rest of the 23 items in the policy have no change, they will continue as investigational. **Update 09-22-2023**: Intracept was presented to TAC on 04/04/2023 and concluded Intracept intraosseous nerve ablation system to treat low back pain as investigational for ALOB. Intracept codes 64628 and 64629 config as experimental with effective DOS 11/01/2023 and to go into production 09-24-2023.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

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At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.