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

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

Status: Review **Last Annual Review Date:** 05/22/2024

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 PHCQC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
05/22/2024	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
05/22/2024	58580	**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. PHP follows MCG A-1039 for ALOB. Use of transcervical, intrauterine ultrasound-guided RFA for the treatment of uterine fibroids known as Sonata is consider experimental.
05/22/2024	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.
05/22/2024	43284 43285	**LINX Reflux Management System** for the management of GERD, considered	Reviewed by TAC Dec 2018. LINX Reflux Management System (a sphincter augmentation device)

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		investigational and is not a covered benefit for **Medicare, Commercial and Medicaid.**	(Ethicon, Bridgewater, NJ) 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.
05/22/2024	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
05/22/2024	** 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.
05/22/2024	****** 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.
05/22/2024	0441T	**Iovera cryonerve block** (with or without image guidance) 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.
05/22/2024	38232 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.
05/22/2024	22869	**Interspinous Process**	PHP follows MCG A-0494, Spinal

Last Reviewed by PHCQC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
	22870 C1821 22867 22868	**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**.	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
05/22/2024	S9090	**Vertebral Axial Decompression (VAX-D)** is a motorized spinal traction device (computer controlled) spinal treatment used to stretch the space between the intervertebral space for internal disc Disruption. VAX-D therapy provides a program of treatments for relief from pain and disability for those patients suffering with low back pain. VAX-D therapy is considered experimental and investigational therefore is not a covered benefit **for Medicare, Medicaid and Commercial** members.	For Medicare PHP follows NCD 160.16 for VAX-D. For Commercial and Medicaid, PHP follows, MCG A-0345 Examples of this type of non-covered procedure include, but are not limited to: The VAX-D Spinal Decompression System in 1996; The Decompression Reduction Stabilization (DRS) System in 1998; The Accu-SPINA System, Axiom Worldwide DRX2000 in 2000; Axiom DRX3000, Axiom DRX5000, the Axiom DRX9000; The Lordex Lumbar Spine System in 2003; SpineRx LDM in 2003; NuChoice Medical Healthstar Elite Decompression Therapy in 2004; The Antalgic-Trak, 2005; The Cert Health Sciences SpineMED Decompression Table 2005; DRX; The Alpha-SPINA System; The Dynatron DX2; The Saunders 3D ActiveTrac; Tru Tac 401; Integrity Spinal Care System; MTD 4000 Mettler Traction Decompression System; or Internal Disc Decompression (IDD) Therapy, also known as Intervertebral Differential Dynamics Therapy). Formerly MPM 9.6.

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05/22/2024	E0830 E0840 E0850 E0849, E0855 E0856, E0860 E0870, E0880 E0890, E0900	**Spine Traction Therapy/Device** is unproven and not medically necessary for treating low back and neck disorders with or without radiculopathy due to insufficient evidence of efficacy for Commercial, Medicaid and Medicare. Medicare is covered for cervical traction only for codes (E0840, E0849, E0850, E0855 and E0860).	For Commercial, Medicaid, Medicare, PHP follows, MCG A-0345 for codes not listed below by LCD (L33823). Medicare is covered for cervical traction only (E0840, E0849, E0850, E0855 and E0860), see LCD (L33823) or NCD 280.1. For all other codes not listed here, see MCG A-0345.
05/22/2024	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.
05/22/2024	0358T	**Bioelectrical Impedance Analysis for Body Composition -** Bioelectrical impedance analysis (BIA) is a noninvasive test that has been proposed as a method for whole body composition assessment (percentage of bone, fat, muscle, and water) or body fat composition assessment (proportion of fat and fat free mass). This test may be performed in conjunction with annual wellness examinations, nutritional evaluations or weight management consultations with an individual's health care provider. Variables such as testing methods, types of equipment and health factors of the individual being evaluated are known to affect results, is considered investigational and is not a covered benefit for **Medicare, Commercial and Medicaid.**	PHP follows MCG (A-0667), for ALOB. Formerly *MPM 5.10*
05/22/2024	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.
05/22/2024	81291	**MTHFR (5,10-methylenetetrahydrofolate reductase)** (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C) is not a covered benefit for **Medicare, Commercial or Medicaid** benefit.	PHP follows CMS, LCD (L36400) MolDX: Genetic Testing for Hypercoagulability Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR), Local Coverage Article (LCA A57571). PHP also follows MCG, Hyperhomocysteinemia, MTHFR Gene (A-0629). There is broad consensus in the medical literature that MTHFR

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			genotyping has no clinical utility in any clinical scenario. Code 81291 was formerly listed in MPM 7.11.
05/22/2024	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).
05/22/2024	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.
05/22/2024	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.
05/22/2024	E0680 E0681 E0677 E0678 E0679 E0682	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 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**	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 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.

Last Reviewed by PHCQC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
		Medicaid.	
05/22/2024	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.
05/22/2024	64628 64629	Thermal destruction (i.e., ablation) of the intraosseous basivertebral nerve (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 and 04/09/2024. 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 for **Medicare, Commercial and Medicaid**
05/22/2024	S2900 20985 0054T 0055T	**Computer-assisted) and Pre-operative advanced imaging** are considered unproven and not medically necessary due to insufficient evidence of efficacy for Medicare, Commercial and Medicaid 1) Computer-assisted musculoskeletal surgical navigation for shoulder arthroplasty; hip arthroplasty (e.g. MAKOplasty/MAKO Tactile Guidance System); and knee arthroplasty (e.g., MAKOplasty) because there is a lack of reliable evidence that it improves surgical outcomes. **Note**: Robotic assistance is considered integral to the primary procedure and not separately reimbursed. 2) Pre-operative advanced imaging where required for any experimental, investigational, or unproven procedure (e.g., where required for computer-assisted surgical navigation, robotic-assisted surgical navigation, or for customized patient implants and/or instrumentation).	PHP considers Computer-Assisted Navigation, such as MAKO and/or Da Vinci **and** Pre-operative advanced imaging as unproven and not medically necessary due to insufficient evidence of efficacy **for Medicare, Commercial and Medicaid** Evidence suggests no significant difference in function, outcomes, or complications in the short term between robotic assisted and conventional arthroplasty. Computer-assisted musculoskeletal surgical navigational orthopedic techniques are not separately covered and are not eligible for payment.
10/23/2024	0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T,0418T, C1824	**CCM®** is the brand name for cardiac contractility modulation, the non-excitatory electrical pulses delivered by the implantable Optimzer device. Unlike a pacemaker or a defibrillator, the OPTIMIZER system is designed to control the	Reviewed by TAC on July 16, 2024. PHP considers the cardiac contractility modulation (CCM) administered by Optimizer device investigational and experimental and/or unproven for all indications, including but not limited to heart failure for ALOB.

Last Reviewed by PHCQC	CPT and HCPCS codes	Investigational or Experimental services	Comments and Definitions
		strength of contraction of the heart muscle rather than the rhythm. The implantable Optimzer device is proposed for the treatment of chronic heart failure with reduced and midrange ejection fractions.	
03-26-2025	64624	**Genicular nerve radiofrequency ablation (GNRFA)** as a technique to alleviate chronic knee pain secondary to osteoarthritis is considered unproven and not medically necessary due to minimal Randomized Controlled Trials (RCTs) with larger sample sizes and long-term follow-up and factors that predict treatment success after GNRFA. Unable to confirm the clinical efficacy for Medicare, Commercial and Medicaid.	Reviewed by TAC on Jan 28, 2025. PHP considers radiofrequency ablation of genicular nerve for treatment of osteoarthritis of the knee is considered investigational and experimental for Medicare, Commercial and Medicaid.
03-26-2025	0627T, 0628T, 0629T, 0630T	**Via Disc NP** is an injectable disc allograft used to treat discogenic low back pain by supplementing degenerative discs.	Injection of allograft into the intervertebral disc for the treatment of degenerative disc disease is considered experimental, investigational and/or unproven, Medicare, Commercial and Medicaid.

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 a Result of Services Which are not Covered Under Medicare (§180); • Excluded foot care services and	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

		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

Population Health & Clinical Quality Committee (PHCQC): Clinton White MD
Senior Medical Directory: Jim Romero MD
Date Approved: 10/23/2024

References

1. **Thermal Intradiscal Procedures (Includes IDET and Nucleoplasty):**
   a) MCG, Thermal Intradiscal Procedures (TIPs), ACG: A-0217(AC), 28th Edition, Last Update: 3/14/2024. [Cited 05/07/2024]
   b) CMS, National Coverage Determination (NCD), for Thermal Intradiscal Procedures (TIPs) (NCD 150.11), Version #1, Date 01/05/209. [Cited 05/07/2024]
   c) CMS, MLN Matters # MM6291, Thermal Intradiscal Procedures, article revised on April 12, 2018. [Cited 05/17/2024]
2. **Sonata:**
   a) **Hayes,** Transcervical Radiofrequency Ablation with the Sonata System for Symptomatic Uterine Fibroids, Health Technology Assessment, Sep 30, 2020 | Annual Review: Jun 26, 2023 [Cited 04/26/2024]
   b) MCG: Transcervical Uterine Ablation of Leiomyomas, ACG: A-1039 (AC), 28th edition, Last Update: 3/14/2024. [Cited 04-26-2024]
   c) ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician Gynecologists, Management of Symptomatic Uterine Leiomyomas, Number 228 (Replaces Practice Bulletin Number 96, August 2008) JUNE 2021. [Cited 04/26/2024]
   d) U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). Sonata® Sonography-Guided Transcervical Fibroid Ablation System. 510 (k) K173703. Accessed May 10, 2021. Availble at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173703.pdf
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   f) Aetna, Number 0304, Fibroid Treatment, Next Review 03-13-2025. [Cited 05-26-2024]
   g) Cigna, Ultrasound-guided Radio Frequency Ablations for Uterine Fibroid, Policy# 0602, effective: 06-15-2023, Next review 06-15-2024. [Cited 05-26-2024]
3. **Subtalar Arthroereisis Implant for Pediatric Patients:**
   a) New Mexico Human Services Department, General Benefit Description, NMAC 8.310.2.12.H.(10)(b), eff: 04/05/2022, [Cited 04/30/2024]
   b) CMS, Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, 290 Foot Care, A Treatment of Subluxation of Foot and 290.B.1 Treatment of Flat Foot, (Rev. 12497, 02/08/2024). [Cited 04/30/2024]
   c) Aetna, Subtalar Implant for Foot Deformity, Number: 0669, Effective: 08-22-2003, Next Review: 07/25/24. (Experimental & investigational for treatment of subtalar instability). [Cited 04/30/2024]
   d) Cigna, Subtalar Joint Implantation Subtalar Arthroereisis, Policy # 0486, Next review date 10/15/2024. [Cited 04/30/2024]
   e) Humana, Extraosseous Subtalar Joint Implantation and Revision Date 02/29/2024, Policy Number: HUM- 0493-014. [Cited 04/30/2024]
   f) Hayes, a TractManager Company, Subtalar Arthroereisis for the Treatment of Pediatric Flatfoot, Feb 16, 2024. [Cited 04/30/2024]
   g) Hayes, Subtalar Arthroereisis for the Treatment of Adult-Acquired Flatfoot Deformity, Feb 15/2024. [Cited 04/30/2024]
4. **LINX Reflux Management System for the Treatment of GERD**
   a) Hayes, Magnetic Sphincter Augmentation LINX Reflux Management System (Ethicon Inc.) for Treatment of GERD, Aug 25, 2023. [Cited 04/30/2024]
   b) MCG, Health Ambulatory Care, 27th Edition, Implantable Magnetic Esophageal Ring (Linx), (ACG: A-0990), Last update:03/14/2024. [Cited 04/30/2024]
   c) Aetna, Gastroesophageal Reflux Disease (GERD): Treatment Devices, Number: 0213, Last review: 04/16/2024, Next review: 02/13/2025. [Cited 04/30/2024]
   d) UHC, Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia, Policy Number: 2023T0322FF, Effective Date: January 1, 2024. [Cited 04/30/2024]

5. **Bronchial Thermoplasty For Treatment of Asthma**
   a) Hayes, a TractManager Company. Bronchial Thermoplasty for Treatment of Asthma, Annual review: Jul 11, 2023. [Cited 05/01/2024]
   b) MCG Health Ambulatory Care 27th Edition, A-0634(AC), Bronchial Thermoplasty, Ambulatory Care, last update: 03/14/24 [Cited 05/01/2024]
   c) Aetna© Clinical Policy Bulletin, # 0744 Bronchial Thermoplasty, Effective 2/8/08. Last Review Last Review 10/06/23, Next Review: 08/08/24. [Cited 05/01/2024].
   d) United Healthcare Commercial Medical Policy, Bronchial Thermoplasty, Policy Number: 2021T0542Q (unproven), Effective Date: Nov 1, 2023 [Cited 05/01/2024]
   e) Cigna, Medical Coverage Policy # 0502, Bronchial Thermoplasty, Next Review Date 07/15/2023. [Cited 04/10/2023]
6. **Percutaneous Neuromodulation Therapy (PNT)**
   a) Hayes, Vertis Pnt™ System (VERTIS NEUROSCIENCE INC.) For Percutaneous Neuromodulation Therapy For Low Back Pain, Health Technology Assessment Jan 10, 2006, annual review: Aug 09, 2008. ARCHIVED Feb 09, 2009 [Cited 05/01/2024]
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    b) Aetna: Artificial Retina and Artificial Iris, Number: 0713, Last review: 10/12/2021, effective 9/30/05, next review: 08/08/2024. [Cited 05/07/2024]
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b) Hayes, Partial Knee Arthroplasty with the Mako Robotic-Arm Assisted Surgery (Stryker) for Treatment of Osteoarthritis, Dec 09, 2022. [Cited 09-18-2023]
c) Hayes, Robotic Assisted Platforms for Hip or Knee Arthroplasty - Product Comparison, Nov 17, 2022. [09-18-2023]
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    i) Humana, Neuroablative Techniques for Chronic Pain, No HUM-0387-024, Date 11-02-2023. [Cited 01-14-2025]
25. **Via Disc NP:**
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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.

05/22/2024 Annual review. Reviewed by Medical Policy Committee on 05/01, 05/03, 05/08, 05/10- 2024. Of the listed investigative procedures items the following items have updates:

- **Acessa, System** – On this review, Acessa will be a covered benefit for ALOB and moved the covered information to Hysterectomy and Radiofrequency Ablation for Uterine Fibroid MPM 8.9. PA will be required for 58674 for ALOB.
- **Sonata:** Code update only. Removed code 0404T it has been deleted and replaced with 58580 on 01/01/2024. Configure new code 58580 as experimental for ALOB. Add language to policy PHP follow MCG A-1039 for ALOB.
- **Iovera cryonerve block:** Code update only. Add new code 0441T- this code is more appropriate code for this service. Some guidance and payers use old codes and some guide to use the new 0441T code. Due to mixed feelings of CPT code usage, we added 64640 to the policy and will start requiring PA for ALOB. Unable to config since it could be used for other areas of the peripheral nerve. Updated coding guidance to include as a note in the MPM to not use 64640 and 64999 for Iovera. Keep code 64999 in the policy for Iovera, since request may come through using this code erroneously. Unlisted code 64999 has high utilization. Because code 64999 is a miscellaneous code it will go through a check point to validate appropriateness and no PA will be required.
- **Stem Cell Therapy for Orthopedic Application:** Code update only. Removed code 38240 since it does not pertain to autologous but to allogeneic.
- **Whole Breast Ultrasound, Semi-Automatic**: remove ABUS from this policy. Rationale: there is no method to monitor for utilization for which breast ultrasonography devices are used for adjunctive screening for breast cancer and the benefit is the same. See MPM 24.1
- **Interspinous Process Decompression (IPD):** Code update only. Add codes: 22867 and 22868 since IPD can also be done as an open approach. Codes 22867 and 22868 will be config as investigational for ALOB.
- **Intervertebral Differential Dynamics Therapy (IDD**): Title changed to Vertebral Axial Decompression (VAX-D). All language for IDD were removed. Removed to follow LCD (L33823) and each line of business will follow as: For Medicare PHP follows NCD 160.16 for VAX-D. For Commercial and Medicaid, PHP follows, MCG A-0345. Added to policy the types of VAD-D. Moved spine traction codes E0830, E0840 and E0850 to the new item called Spine Traction Therapy/Devices.
- **Spine Traction Therapy/Device:** (New item) Spine Traction is unproven and not medically necessary for treating low back and neck disorders with or without radiculopathy due to insufficient evidence of efficacy for Commercial, Medicaid and Medicare. Medicare is covered for cervical traction only for codes (E0840, E0849, E0850, E0855 and E0860) which will follow either LCD

(L33823) or NCD (280.1). Reconfig codes: E0840 & E0850 to pay for Medicare. Config codes: E0849, E0855, E0856, E0860, E0870, E0880, E0890, E0900, as experimental for commercial and Medicaid. Config E0856, E0870, E0880, E0890, E0900 as investigational for Medicare.

- **Bioimpedance Spectroscopy (BIS) for the Assessment of Lymphedema (code 93702):** This item has been moved to Lymphedema and Lipedema Surgical Treatment, MPM 62.0 as a covered service.
- **Bioelectrical Impedance Analysis (BIA) for Body Composition (code 0358T):** (new item) BIA is considered experimental and will follow MCG A-0667. BIA is a noninvasive test that has been proposed as a method for whole body composition assessment (percentage of bone, fat, muscle, and water) or body fat composition assessment (proportion of fat and fat free mass).
- **External upper limb stimulators tremor stimulator:** (item removed from policy and moved **to** Peripheral Nerve Stimulation, MPM 53.0). Non-coverage will continue to apply to Commercial and Medicaid only. Upon this review, Medicare has released a new Local Coverage Determination (LCD), effective for services performed on or after 04/07/2024, that lists codes E0734 and A4542 as a covered item in LCD (L39591) & LCA (A59680), please see Peripheral Nerve Stimulation, MPM 53.0 for details.
- **Koya Dayspring System**: Code update only. Removed deleted code K1024. Add codes: E0680, E0681, E0677, E0678, E0679, E0682, which will be configured as investigational/experimental for ALOB.
- **Thermal destruction (i.e., ablation) of the intraosseous basivertebral nerve (BVN) (Intracept ® Procedure):** Configured for ALOB, Thermal destruction of intraosseous basivertebral nerve codes: 64628 and 64629 as investigational for ALOB. Continue configuration of CPT codes: 64628 and 64629- as investigational for ALOB. TAC deemed it investigational on 04/04/2023. Add language to say non-coverage includes ALOB.
- **Computer-assisted) and pre-operative advanced imaging**: New item. Reviewed by Medical Policy Committee 09-22-2023. Computer-Assisted Navigation, such as MAKO and/or Da Vinci and Pre-operative advanced imaging are considered unproven and not medically necessary due to insufficient evidence of efficacy for Medicare, Commercial and Medicaid. Evidence suggests no significant difference in function, outcomes, or complications in the short term between robotic assisted and conventional arthroplasty. Config S2900, 20985, 0054T, 005T as investigational for ALOB.

Update on 09-20-2024: Reviewed by Medical Policy Committee on 09-20-2024. Approved TAC decision made on July 16, 2024, who considered the cardiac contractility modulation (CCM) administered by Optimizer device investigational and experimental and/or unproven for all indications, including but not limited to heart failure, for ALOB. Codes related to insertion, removal or replacement of a cardiac contractility modulation (CCM) devices are considered experimental, investigational and/or unproven: 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, and C1824. These codes will be configured as investigational.

Update on 01/22/2025: Reviewed by Medical Policy Committee on 01/17 & 01/22/2025. Removed PA for 64640 for ALOB and remove coding advice language "*Do not use codes 64640 and 64999 for Iovera*" under Iovera section. Update to be included in Oct cycle.

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***

Web links:
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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.