

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: 05-28-2025

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
 - o 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®. MCG has provided a tool that allows Presbyterian Health Plan members and
 prospective members to view relevant MCG guidelines, however you will not be able to print them. Follow the
 instructions provided at MCG Care Guideline to access the MCG 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 Note: MCG has provided a tool that allows Presbyterian Health Plan members and prospective members to view relevant MCG guidelines, however you will not be able to print them. Follow the instructions provided at MCG Care Guideline to access the MCG Guidelines. |
|---------------------------|----------------------------------|--|---|
| 05/28/2025 | 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) for Medicare and Medicaid. |
| 05/28/2025 | 58580 | Sonata, a transcervical approach 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 considered experimental. |
| 05/28/2025 | 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 | PHP follows Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, 290 Foot Care for ALOB, see also NMAC 8.310.2.12.H.(10).(b). |

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| | | 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. | |
| 05/28/2025 | 43284 43285 | LINX Reflux Management System for the management of GERD, considered investigational and is not a covered benefit for Medicare, Commercial and Medicaid. | Reviewed by TAC Dec 2018. LINX Reflux Management System (a sphincter augmentation device) (Ethicon, Bridgewater, NJ) investigational for the management of GERD and all other indications. PHP follows MCG Criteria # A-0990, Implantable Magnetic Esophageal Ring (LINX). |
| 05/28/2025 | 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. |
| 05/28/2025 | ** 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. |
| 05/28/2025 | ** 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 sufficient published evidence to assess the impact of PNT | Percutaneous neuromodulation therapy for the treatment of low back pain . 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). |

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| | | which includes Biowave's Deepwave percutaneous neuromodulation pain therapy system at this time. | |
| 05/28/2025 | 0441T C9809 | lovera cryonerve block (cryoneurolysis) (with or without image guidance) procedure for the treatment of knee pain including the use of lovera for pain management before and after total knee arthroplasty, since it is considered investigational and experimental because the effectiveness of these approaches has not been established 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. |
| 05/28/2025 | 38232 38241 (both codes require PA) | Stem Cell Therapy for Orthopedic Application: - Autologous stem cell therapy for treatment of osteoarthritis (e.g., knee, hip, ankle, shoulder), avascular necrosis of the hip and treatment of bone non-union 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 therapyConsidered investigational for most payers for Mesenchymal stem cells. |
| 05/28/2025 | 22869 22870 C1821 22867 22868 | 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. Formerly MPM 25.0 Interspinous decompression devices and interlaminar stabilization devices include but are not limited to the following: |

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| 05/28/2025 | 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 |
| 05/28/2025 | E0830, E0840, E0849, E0850, 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 home or outpatient usage for Commercial, Medicaid and Medicare. | For Commercial, Medicaid, Medicare, PHP follows, MCG A-0345 for codes not listed below by LCD (L33823). Medicare covers 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. |
| 05/28/2025 | C1839, 66683 | CUSTOMFLEX Artificial Iris for aniridia considered investigational for all LOB because of insufficient scientific evidence of their safety and effectiveness. | Reviewed by TAC on April 17, 2019 to label Customflex artificial iris as investigational. |
| 05/28/2025 | 0358T | Bioelectrical Impedance Analysis for Body Composition - Bioelectrical impedance analysis (BIA) is a noninvasive test that has been | PHP follows MCG (A-0667), for ALOB. |

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| | | 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. | |
| 05/28/2025 | 95012 | Nitric Oxide Breath Analysis for the Diagnosis and management 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. |
| 05/28/2025 | 81291 | MTHFR (5,10-methylenetetrahydrofolate reductase) for arterial or venous thromboembolic disease; for pregnancy complications or adverse outcomes; for psychiatric conditions, evidence is insufficient (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) MoIDX: Genetic Testing for Hypercoagulability Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR), Local Coverage Article (LCA A57571) for Medicare. PHP follows MCG, Hyperhomocysteinemia, MTHFR Gene (A-0629) for Medicaid and Commercial. There is broad consensus in the medical literature that MTHFR genotyping has no clinical utility in any clinical scenario. |
| 05/28/2025 | 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 for ALOB: 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). |

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| 05/28/2025 | 0378T, 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 agerelated macular degeneration (ARMD)-associated choroidal neovascularization and for all other indications. |
| 05/28/2025 | 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 Medicaid. | 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. |
| 05/28/2025 | 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. |
| 05/28/2025 | 64628 | Thermal destruction (i.e., | Reviewed by TAC on 04-04-2023 |

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| Last Reviewed by PHCQC | CPT and HCPCS codes | Investigational or Experimental services | Comments and Definitions Note: MCG has provided a tool that allows Presbyterian Health Plan members and prospective members to view relevant MCG guidelines, however you will not be able to print them. Follow the instructions provided at MCG Care Guideline to access the MCG Guidelines. |
| | 64629 | 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. | 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 |
| 05/28/2025 | \$2900 20985 0054T 0055T | Computer-assisted surgical navigation for orthopedic procedures specific to the pelvis and appendicular skeleton, including but not limited to use during a MAKOplasty procedure, is considered experimental, investigational and/or unproven. for Medicare, Commercial and Medicaid. | 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. |
| 05/28/2025 | 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 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. | 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. |

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| 5/28/2025 | 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. |
| 05/28/2025 | 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. |
| 05-28-2025 | 0600T 0601T | Nanoknife Irreversible Electroporation (IRE) for tissue ablation for treatment of prostate cancer is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer- reviewed medical literature. | Reviewed by on TAC 04/15/2025 PHP considers Nanoknife Irreversible Electroporation (IRE) for treatment of prostate cancer investigational and experimental for Medicare, Commercial and Medicaid. |

| | Other related sources for non-covered services | | | |
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| 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 | 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, (Rev. 198, 11-06-14) US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15(o), up to date as of 4/17/2025. Title 42 was last amended 4/15/2025. Experimental or investigational | |

| | | 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 supportive devices for feet (§30); or, Excluded investigational devices (See Chapter 14) | |
|-----|--------------------------|---|--|
| N/A | No specific codes. | For Medicare: When these services are provided in the context of an approved IDE, they will be considered reasonable and necessary. 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: <u>Jim Romero MD</u> Medical Director: Kresta Antillon MD

Date Approved: 05-28-2025

References

1. Thermal Intradiscal Procedures (Includes IDET and Nucleoplasty):

- a) MCG, Thermal Intradiscal Procedures (TIPs), ACG: A-0217(AC), 29th Edition, Last Update: 1/25/2025. [Cited 04-19-2025]
- b) CMS, National Coverage Determination (NCD), for Thermal Intradiscal Procedures (TIPs) (NCD 150.11), Version #1, Date 01/05/209. [Cited 04-19-2025]
- c) CMS, MLN Matters # MM6291, Thermal Intradiscal Procedures, article revised on April 12, 2018. [Cited 04-19-2025]
- Aetna, Intradiscal Procedures, Number 0602, Last Review: 03/14/2025, effective: 03/15/2002, Next review: 06/26/2025, [Cited 04-19-2025]
- e) NM BCBS of NM, Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty, Policy#SUR712.023, Effective date: 09-15-2024. [Cited 04-19-2025]

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 [Cited04-19-2025]
- MCG: Transcervical Uterine Ablation of Leiomyomas, ACG: A-1039 (AC), 29th edition, Last Update: 01/25/2025.
 [Cited 04-19-2025]
- 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 04-19-2025]
- 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
- e) 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. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173703.pdf
- f) Aetna, Number 0304, Fibroid Treatment, Next Review 03-13-2025. [Cited 04-19-2025]

- g) Cigna, Ultrasound-guided Radio Frequency Ablations for Uterine Fibroid, Policy# 0602, effective: 06-15-2023, Next review 06-15-2024. [Cited 04-19-2025]
- h) Humana, Uterine Fibroid Surgical Treatments, Policy Number: HUM-0321-025, revision date: 03/28/2024. [Cited 04/22/2025]

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:01/01/2025, [Cited 04/19/2025]
- b) CMS, Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, <u>290 Foot Care</u>, A
 Treatment of Subluxation of Foot and 290.B.1 Treatment of Flat Foot, (Rev. 12497, 02/08/2024). [Cited04/19/2025]
- c) Hayes, Subtalar Arthroereisis for the Treatment of Pediatric Flatfoot, Feb 16, 2024. [Cited 04/19/2025]
- d) Hayes, Subtalar Arthroereisis for the Treatment of Adult-Acquired Flatfoot Deformity, Feb 15/2024. [Cited 04/19/2025]
- e) Aetna, Subtalar Implant for Foot Deformity, Number: 0669, Effective: 08-22-2003, Next Review: 07/24/2025. (Experimental & investigational for treatment of subtalar instability). [Cited 04/19/2025]
- f) Cigna, Subtalar Joint Implantation Subtalar Arthroereisis, Policy # 0486, Next review date 10/15/2025. [Cited 04/19/2025]
- g) Humana, Extraosseous Subtalar Joint Implantation and Revision Date 02/29/2024, Policy Number: HUM- 0493-016. [Cited 04/19/2025]

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, Sep 20, 2024. [Cited 04/19/2025]
- MCG, Health Ambulatory Care, 29th Edition, Implantable Magnetic Esophageal Ring (Linx), (ACG: A-0990), Last update:01/25/2025. [Cited 04/19/2025]
- c) Aetna, Gastroesophageal Reflux Disease (GERD): Treatment Devices, Number: 0213, Last review: 04/16/2024, Next review: 02/13/2025. [Cited 04-19-2025]
- d) UHC, Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia, Policy Number: 2025T0322II, Effective Date: January 1, 2025. [Cited 04/19/2025]
- e) CMS, National Government Services, Select Minimally Invasive GERD Procedures, LCD (L35080) Revision Date 02/10/2022 R12, related LCA (A56863), revision date: 10/01/2020 R3. [Cited 04-19-2025]
- f) CMS, Palmetto LCD (L39780) Lower Esophageal Magnetic Sphincter Augmentation and related article LCA (A59654), effective 05/21/2024. [Cited 04-19-2025]

5. Bronchial Thermoplasty For Treatment of Asthma

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Publication History

- 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.

- 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.
- 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.
- O5-25-22 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.
 - o Now follow CGS LCD (L33823) and LCA (A52476).
 - o 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.
 - o 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.
 - **lovera 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 lovera. Keep code 64999 in the policy for lovera, 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 Preoperative 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 lovera*" under lovera section. Update to be included in Oct cycle.

Update on 03-26-2025:

- Genicular nerve radiofrequency ablation (GNRFA): Reviewed by Medical Policy Committee on 01/31/2025 after TAC on 01/28/2025. 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. CPT code 64624 will be configured as Investigational and Experimental for ALOB.
- Via Disc NP: Reviewed by Medical Policy Committee on 02-05-2025. Via Disc NP (Vivex Biologics Inc.) for Relief of Intervertebral Disc Degeneration Symptoms: 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. Codes 0627T, 0628T, 0629T, 0630T and 64624 will be config as Investigational and Experimental for ALOB.
- 05-28-2025 Annual review. Reviewed by Medical Policy Committee on 04-23-2025, 04-25-2025, 04-30-2025 and 05-09-2025. Update to add: MCG has provided a tool that allows Presbyterian Health Plan members and prospective members to view relevant MCG guidelines, however you will not be able to print them. Follow the instructions provided at MCG Care Guideline to access the MCG Guidelines.
 - Thermal Intradiscal Procedures (TIPs) (includes IDET & Nucleoplasty), (Percutaneous thermal intradiscal remains investigational and experimental for ALOB. Updated policy with minor language about missing information to include Medicaid to follow NCD 150.11 along with Medicare.

Commercial will continue to follow MCG. CY 2020, CPT codes: 22526, 22527 configured as investigational and experimental ALOB.

- Sonata- Remains investigational and experimental for ALOB. Continue to follow MCG A-1038 for ALOB. Consider TAC review for possible coverage. CY 2024 - Configured code 58580 as investigational and experimental for ALOB
- Subtalar Arthroereisis Implant Remains investigational and experimental for ALOB. Added language to identify PHP follows Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, 290 Foot Care for ALOB. Codes S2117,0335T, 0510T, & 0511T configured as investigational and experimental for ALOB.
- LINX- Remains investigational and experimental for ALOB. Continue to follow MCG Criteria # A-0990 for ALOB. Noted CMS has a new coverage LCDs not within our region recently released. PHP will wait for CMS in our region to provide an LCD similar to Palmetto before considering coverage for Medicare. Consider TAC review for possible coverage. Codes 43284 and 43285 are configured as investigational and experimental for ALOB.
- Bronchial Thermoplasty (BT) for treatment of Asthma Remains investigational and experimental for ALOB. Continue to follow MCG A-0634 for ALOB. Codes 31660 and 31661 configured as investigational and experimental for ALOB.
- Secca Remains investigational and experimental for ALOB. There remains to be no guidance by CMS or MCG. There is no specific CPT code for Secca. In CY 2020, CPT: 46999 configured to not pay for ICD-10: R15.0 thru R15.9 and F98.1 for ALOB.
- Percutaneous Neuromodulation Therapy (PNT for treatment of low back pain— Remains
 investigational and experimental for ALOB. Updated language to remove "PHP follows retired LCA
 (A56062) and Hayes" then replaced to say, "there is no sufficient published evidence to assess the
 impact of PNT".
- lovera Cryonerve Block Remains investigational and experimental for ALOB. There remains to be
 no guidance by CMS or MCG, most likely because the effectiveness of these approaches has not
 been established The policy was updated with language to identify treatment of location and purpose
 "for the treatment of knee pain including the use of lovera for pain management before and after total
 knee arthroplasty,"

Added HCPCS code C9809 which will be configured as investigational and experimental for ALOB. Code 0441T configured as investigational and experimental for ALOB

• Stem Cell Therapy for Orthopedic Application – Remains investigational and experimental for ALOB. Policy updated with language to identify treatment of additional location "of osteoarthritis (e.g., knee, hip, ankle, shoulder), and treatment of bone non-union" also removed language specific to hip "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"

Code 38232 and 38241 will continue to require PA. Note: The use of stem Cell technology is not managed by Optum.

- Interspinous Process Decompression- remains to be I&E for ALOB. Continue to follow MCG A-0494, Spinal Distraction Devices for ALOB. CY 2021 Configured 22869, 22870, C1821 as investigational and experimental for ALOB; CY 2024 Configured 22867, 22868 as investigational and experimental for ALOB.
- Vertebral Axial Decompression (VAX-D) remains to be investigational and experimental for ALOB.
 Medicare will continue to follow NCD 160.16. Commercial and Medicaid, will continue to follow MCG A-0345. Related code (S9090) will be configured as investigational and experimental for ALOB.
- Spine Traction Therapy/Device- Remains I&E for ALOB. Policy updated with language "home or outpatient usage" to identify what setting these traction devices are non-covered. Spine Traction Therapy Device for treating low back and neck disorders for Commercial, Medicaid, Medicare remains investigational and experimental as described by the breakdown of coverage information by line of business:
 - For Commercial and Medicaid, PHP follows, MCG A-0345

 for non-covered codes (E0830, E0840, E0849, E0850, E0855, E0856, E0860, E0870, E0880, E0890, E0900, E0941)
 - For Medicare PHP follows MCG A-0345 for non-covered codes (E0830, E0856, E0870, E0880, E0890, E0900, E0941)
 - For Medicare PHP follows Cervical Traction Devices, LCD (L33823) for covered HOME cervical traction for (E0840, E0849, E0850, E0855 and E0860)

CY 2020: codes E0830, E0840, E0850 configured to not pay for all LOB

CY 2024 reconfigured codes E0840 & E0850 to Pay for Medicare

CY 2024: codes: E0849, E0855, E0856, E0860, E0870, E0880, E0890, E0900 configured as investigational and experimental commercial and Medicaid.

Re-request to configure code E0830 as investigational and experimental for ALOB.

 CUSTOMFLEX Artificial Iris for aniridia- remains to be investigational for ALOB. Changed includes code update: Remove deleted codes 0617T, 0616T, 0618T and replace with newly released code 66683 effective 01/01/2025. Added code 66683 which will be configured as investigational and experimental for ALOB.

- Bioelectrical Impedance Analysis (BIA) for Body Composition
 - Continue with no change, Bioelectrical Impedance Analysis (BIA) for body composition remains investigational and experimental for ALOB
 - Code 0358T configured as investigational and experimental for ALOBs.
- Nitric Oxide Breath Analysis for the Diagnosis and Management of Asthma
 - Continue as investigational and experimental for ALOB.
 - Added language: On this review PHP included the "management" of asthma is also considered investigational and experimental.
 - CPT code 95012 configured as investigational and experimental for ALOB
- MTHFR remains investigational and experimental for ALOB
 - Added "Medicaid & commercial" to follow MCG.
 - Added language what MTHFR does not support: "For arterial or venous thromboembolic disease; for pregnancy complications or adverse outcomes; for psychiatric conditions, evidence is insufficient"
 - Code 81291 configured as investigational for ALOB.
- Fetal chromosomal microdeletion with cell-free DNA remains investigational and experimental for ALOB.
 - Added we follow ACOG for ALOB.
 - On this review, code (81422) will be config as investigation & experimental for ALOB.
- ForeseeHome remote monitoring remains investigational and experimental for ALOB
 - Code 0379T configured as investigational and experimental for ALOB
 - Added code 0378T to policy which will be configured as investigational and experimental for ALOB
- Pigmented Lesion Assay (PLA): PLA has been removed from this policy and moved to MPM 7.7,
 Genetic Testing for Cutaneous Melanoma since Medicare and Medicaid will now be covered to follow LCD (L38178). The commercial line of business will remain investigational and experimental.
- The Koya Dayspring System: remains investigational and experimental for ALOB
 - CY 2024 configured E0677, E0678, E0679, E0680, E0681, E0682, and as investigational and experimental for ALOB
- 3D Printing, remains investigational and experimental for ALOB
 - Codes 0559T, 0560T, 0561T, 0562T configured as investigational and experimental for ALOB
- Intracept Procedure: remains investigational and experimental for ALOB
 - Codes 64628 and 64629 are configured as investigational and experimental for ALOB.
- Computer-assisted surgical navigation: Language description in the policy was updated to be
 more generalized, instead of saying it only pertains to Hip, Knee or Shoulder, it was updated to
 pertain to "orthopedic" procedures. Continuing with no change, the use of computer-assisted
 surgical navigation for orthopedic procedures including but not limited to use during a MAKOplasty
 procedure remains investigational and experimental for ALOB. CY 2024 codes S2900, 20985,
 0054T, 0055T config as investigational and experimental for ALOB.
- Cardiac Contractility Modulation- CCM®: remains investigational and experimental for ALOB. Codes 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, C1824 configured as investigational and experimental for ALOB.
- Genicular nerve radiofrequency ablation (GNRFA): remains investigational and experimental for ALOB. Code 64624 (GNRFA) configured as investigational and experimental for ALOB
- Via Disc NP Continuing with no change, the use of Via Disc NP remains investigational. Codes: for 0627T, 0628T, 0629T, 0630T and 64624 are configured as investigational and experimental for ALOB.
- Nanoknife: NEW. Irreversible Electroporation (IRE) for tissue ablation for treatment of prostate
 cancer is considered experimental/investigational for ALOB. Code 0600T will be configured as
 investigational and experimental for ALOB.

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:

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.