

Medical Policy

Policy: 202407

Effective Date: 12/19/2024

SUBJECT: Not Standard of Care

Annual Review Date: 12/12/2024

Last Revised Date: 12/19/2024

**SERVICES IN THIS LIST OF CORPORATE MEDICAL POLICIES ARE
CONSIDERED NOT STANDARD OF CARE**

Definition: Not standard of care describes a drug, medical device, treatment, or procedure that is considered not appropriate regarding standards of good medical practice, is used primarily for purposes of convenience, or may be considered an inappropriate level of service that can be safely provided.

When determining a status of not standard of care, the Company considers information from multiple sources, including but not limited to published, peer-reviewed literature; clinical practice guidelines published by consortia of medical organizations; commercial health technology assessment organizations such as Hayes, a symplr Offering; position statements from specialty and sub-specialty societies; and UpToDate. Please see the Healthcare Technology Assessment Program Description for more details: <https://www.medmutual.com/-/media/908301A8044D420BB377375914643593.ashx>.

This Corporate Medical Policy applies to commercial lines of business as well as Medicare Advantage when there is no National Coverage Determination, Local Coverage Determination, or other guidance published by the Centers for Medicare & Medicaid Services.

To access MCG Care Guidelines, please see: <https://medmutual.access.mcg.com/index>.

Medical Necessity: Based upon our findings, the Company has determined that the following services have not been accepted in the medical community as the standard or appropriate means of treatment for these conditions. The Company considers the following services as indicated by the Applicable Code(s) or other related code(s) not listed here **not standard of care and not** eligible for reimbursement.

| POLICY NUMBER | TITLE | DESCRIPTION | APPLICABLE CODE(S) | EFFECTIVE/REVISED DATE |
|---------------|---|--|--|------------------------|
| 200211 | Breast Cancer Screening and Diagnostic Procedures (Breast Ductal Lavage and | Breast ductal lavage,-fiberoptic ductoscopy, mammary ductoscopy, and breast duct endoscopy (i.e Acueity System, Acueity, Inc., Larkspur, CA) are utilized to evaluate individuals at high risk for breast cancer. These procedures | CPT 19499 [†] [†] When <i>unlisted procedure, breast</i> (19499) is determined to be breast ductal lavage or fiberoptic ductoscopy. | 09/20/2024 |

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| | Fiberoptic Ductoscopy) | <p>are intended to be used in conjunction with routine clinical breast examination and mammography for early detection and histopathologic diagnosis of nonpalpable breast cancers.</p> <p>Breast ductal lavage is a technique in which epithelial cells (nipple aspirate fluid) are collected from the breast ductal system for cytological analysis. Mild suction is applied to the nipple to identify fluid-yielding duct(s). A microcatheter is then advanced through a duct orifice into the duct(s) and a saline solution is introduced. Saline and cellular material are withdrawn through the catheter and collected in a syringe for cytologic examination. Ductal fluid is analyzed to detect cytological abnormalities suggestive of breast cancer.</p> <p>Fiberoptic ductoscopy is performed by inserting a fiberoptic microendoscope into a ductal orifice and advancing the scope under direct visualization. Abnormal intraductal areas are either biopsied or marked for image-guided core biopsy.</p> | | |
| 200520 | Urinary Incontinence and Overactive Bladder Treatments | <p>There are many types of devices, supplies and procedures targeted at treating urinary incontinence and overactive bladder.</p> <p>Extracorporeal magnetic stimulation is pulsed magnetic stimulation of sacral and/or pudendal nerves to facilitate contractions of pelvic floor muscles. Therapy is intended to strengthen pelvic floor musculature, thus reducing urinary</p> | <p>CPT 53899[†] HCPCS Codes E0175, E0716</p> <p>[†]When <i>unlisted procedure, urinary system</i> – is determined to be extracorporeal magnetic stimulation for urinary incontinence.</p> | 11/24/2024 |

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| | | incontinence. In addition, numerous Kegel exercise assistance devices are available without a prescription and over the counter (e.g. Flyte). The goal of these devices is to guide the user through pelvic floor muscle contractions with vibrations and/or electrical prompting. | | |
| 200522 | Percutaneous or Endoscopic Epidural Adhesiolysis - Chronic Low Back Pain | <p>Epidural adhesiolysis (epidural neuroplasty) is a minimally invasive surgical procedure performed percutaneously or by spinal endoscopy for treatment of chronic post-surgical back pain unresponsive to conventional medical therapy.</p> <p>Percutaneous epidural adhesiolysis (percutaneous adhesiolysis, percutaneous lysis of epidural adhesions) involves inserting a needle into the epidural space at the spinal level where fibrosis, scar tissue or adhesions are suspected. Disruption of adhesions believed to be responsible for symptoms is attempted by introducing a catheter through the needle and injecting various solutions (e.g., hypertonic saline, enzyme, steroid, anesthetic) or by mechanical manipulation of the catheter.</p> <p>Endoscopic epidural adhesiolysis (epiduroscopy, spinal endoscopy with epidural adhesiolysis) is similar to the percutaneous technique with the added theoretical advantage of directly visualizing the epidural space while disrupting adhesions and delivering</p> | <p>CPT 62263, 62264 and 64999[†]</p> <p>[†]When <i>unlisted procedure, nervous system</i> (CPT Code 64999) – is determined to be a Percutaneous or Endoscopic Epidural Adhesiolysis</p> | 12/10/2024 |

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| | | injected drugs to target areas. The procedure is performed following failure of percutaneous epidural adhesiolysis. | | |
| 201022 | Spinal Unloading Device (Lumbar) | A spinal unloading device is intended as a conservative treatment for subacute and chronic low-back pain or scoliosis and can be patient- or therapist-operated. Patient-operated devices provide a traction-effect by shifting weight from the lower back onto the hips, whereas therapist-operated devices apply distracting forces to the spine. Patient-operated devices include, but are not limited to, Orthotrac Pneumatic Vest (Orthofix Inc.) and LTX 3000 (Spinal Designs International Inc.) | HCPCS E0830†, E1399†, and L1499† †When ambulatory traction device, all types, each (E0830), durable medical equipment, miscellaneous (E1399), or spinal orthosis, not otherwise specified (L1499) is determined to be spinal unloading device (lumbar). | 02/26/2025 |
| 201105 | Prolotherapy | Prolotherapy for musculoskeletal conditions involves the injection of sclerosing solutions into or around joints, muscles, or ligaments. Solutions, such as dextrose-glycerine-phenol, Sarapin® (High Chemical Company, Levittown, PA), sodium morrhuate, psyllium seed oil, and zinc sulfate are used to induce an inflammatory reaction, spurring new fibrous tissue growth. This approach aims to stabilize injured joints and ligaments, thereby reducing chronic musculoskeletal pain. | HCPCS M0076 | 09/06/2024 |
| 201324 | Thermography | Thermography (temperature gradient studies) is a non-invasive imaging technique designed to measure and | CPT Code 93740, 76499† | 12/10/2024 |

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| | | display infrared or heat energy emanating from the skin surface. This technique is reported to demonstrate temperature differences that may be due to altered blood flow across various organs and tissues and is intended to assist in the diagnosis of numerous diseases. | ICD-10-PCS Procedure Code 4A0.ZXKZ †When <i>unlisted diagnostic radiographic procedure</i> (76499) is determined to be thermography. | |
| 201535 | Noninvasive Rupture of Membranes Testing in Pregnancy | The fetal membranes protect the developing fetus during pregnancy. Tearing or rupture of the membranes (ROM) can occur normally during labor, but when this occurs prior to 37 weeks of gestation it is considered premature ROM (PROM). Noninvasive tests have been developed to assess suspected PROM. These assays detect the presence of specific placental proteins in vaginal fluid that are only present when the membrane is ruptured. The test is intended to aid in the detection of ROM in pregnant women with signs, symptoms or complaints suggestive of premature rupture. In most cases PROM can be diagnosed based on the patient's history and physical examination. | CPT Codes 84112. | 12/10/2024 |
| 201537 | Radiofrequency Treatment for Pain -Radiofrequency ablation for sacroiliac joint - Radiofrequency ablation for complex regional | Radiofrequency treatment involves the use of an electrical current produced by a radio wave to heat a small area of nerve tissue. The heat from the radio wave is then thought to decrease pain signals from the specific area of treatment. Pulsed radiofrequency (cold radiofrequency, pulsed radiofrequency ablation) is a type of radiofrequency treatment during which a generator delivers bursts of radiofrequency current | CPT 20999†, 22899, 64625, 64627, 64628, 64629, 64640†, 64999†, C9752, and C9753 †When <i>unlisted procedure, musculoskeletal system</i> (20999), <i>destruction by neurolytic agent, destruction by neurolytic agent, other peripheral nerve or branch</i> (64640), or <i>unlisted procedure, nervous system</i> (64999) is determined to be | 08/13/2024 |

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| | <p>pain syndrome (CRPS)</p> <ul style="list-style-type: none"> - Pulsed Radiofrequency for Chronic Pain - Intraosseous ablation of the basivertebral nerve (e.g., the Intracept® Procedure) | <p>to specific nerves. Targeted nerves are not destroyed and the mechanism of action is not well understood.</p> <p>NOTE: The Company uses MCG™ Care Guideline® A-1047, Neurolysis, Genicular Nerve for guidance on radiofrequency ablation for the genicular nerve.</p> | radiofrequency treatment for pain as described in this policy. | |
| 201621 | <p>Pneumatic Compression Device</p> <ul style="list-style-type: none"> - Pneumatic Compression of Trunk and Chest | A pneumatic compression device consists of an air inflatable garment and an electrical pump that intermittently compresses the affected area. The device is intended to reduce abnormal fluid accumulation associated with lymphedema, chronic venous insufficiency with venous stasis ulcer(s) and arterial insufficiency. | HCPCS Codes E0656 and E0657 | 08/27/2024 |
| 201709 | Transanal Radiofrequency Therapy for Fecal Incontinence | Transanal radiofrequency therapy (Secca®, Mederi Therapeutics, Inc., Greenwich, CT) has been reported as a minimally invasive treatment for fecal incontinence when conventional treatment has failed. Radiofrequency energy is delivered to the anal canal sphincter muscle complex, producing thermal-induced local injury. As tissue healing occurs over several months, anal canal tone is reported to increase with resultant decreased fecal incontinence. | <p>CPT 46999[†]</p> <p>[†]When <i>unlisted procedure, anus</i> (46999) is determined to be transanal radiofrequency therapy for fecal incontinence.</p> | 12/10/2024 |

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| 2019-C | REGENETEN Bioinductive Implant | REGENETEN Bioinductive Implant is a graft derived from bovine Achilles tendon that supports the formation of new tendinous tissue for treatment of rotator cuff disease. The patch is surgically inserted and absorbs within roughly 6 months leaving a layer of new tendinous tissue to augment the existing tendon while disrupting disease progression. | CPT Code 29827 [†] , HCPCS code C1713 [†] , C1763 [†] [†] Considered investigational, not standard of care and not eligible for reimbursement when <i>Arthroscopy, Shoulder; with rotator cuff repair (CPT 29827), Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable) (HCPCS C1713) or Connective Tissue, Non/Human (includes Synthetic (HCPCS C1763) is determined to be Regeneten Bioinductive Implant</i> | 12/10/2024 |
| 2019-D | Computer Assisted Musculoskeletal Surgical Navigation System | Computer assisted musculoskeletal surgical navigation system refers to a computer tracking system that assists with preparation and alignment during surgical procedures. Computer assisted navigation can be image based or non-image based. | CPT 20985, 0054T, 0055T | 04/08/2025 |
| 201942 | Bulking Agents for Fecal Incontinence - Solesta® | Solesta® (Oceana Therapeutics, Inc., Edison, NJ) is a biocompatible bulking agent administered by submucosal trans-anal injection. Solesta® may enhance perianal tissue bulking, resulting in narrowing of the anal opening and improved muscle control, thereby reducing involuntary loss of feces. Solesta® is intended for individuals 18 years and older who have failed conventional therapy for fecal incontinence. | CPT 46999 [†] and HCPCS L8605 [†] When unlisted procedure – anus (46999) is determined to be injection of bulking agents for fecal incontinence (Solesta®) | 03/11/2025 |

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| 202401 | Outdated Jaw Reconstruction Procedures | Jaw reconstruction is the process of repositioning severely misaligned upper or lower jaw bones. While this is most often done out of medical necessity, many outdated procedures exist that are no longer standard of care. These include reconstruction of the lower jaw without fixation as well as certain procedures for reconstruction of mandible or maxilla using certain implants. | CPT Codes 21195, 21244, 21245 | 3/11/2025 |
| A-0217 | Thermal Intradiscal Procedures (TIPs) MCG™ Care Guideline® 28 th Edition | Minimally invasive techniques utilized in the management of chronic discogenic low back pain refractory to conventional medical therapy. These procedures include: Intradiscal electrothermal therapy (IDET™), Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), and Disc biacuplasty. | CPT 22526, 22527, 22899 [†] and 64999 [†] [†] When <i>unlisted procedure, spine</i> (22899) or <i>unlisted procedure, nervous system</i> (64999) is determined to be percutaneous intradiscal radiofrequency thermocoagulation and disc biacuplasty. | 12/10/2024 |
| A-0335 | Continuous Passive Motion (CPM) MCG™ Care Guideline® 28 th Edition | Continuous passive motion (CPM) devices provide continuous passive mobilization of a joint in the immediate post-operative period. CPM devices aim to maintain, restore, or increase joint range of motion by mechanically inducing passive movement of the joint, thereby improving mobility as an adjunct to conventional physiotherapy. | HCPCS Codes E0935, E0936 | 12/10/2024 |
| A-0630 | Platelet-Rich Plasma MCG™ Care Guideline® 28 th Edition | Platelet-rich plasma (autologous platelet concentrate, autologous platelet gel) represents concentrated autologous human platelets suspended in a small volume of plasma. Platelets contain numerous growth factors including platelet-derived growth factors and transforming growth factors. These | CPT Codes 0232T and 69620 [†] HCPCS G0460, G0465, P9020 [†] When <i>myringoplasty</i> (69620) is determined to be | 12/10/2024 |

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| | | <p>growth factors are thought to promote wound and soft tissue (i.e., ligament, tendon) repair and healing as well as to stimulate new bone formation. It has been suggested that wound, soft tissue, or bone healing can be accelerated by application of concentrated preparations of platelets containing high quantities of these growth factors.</p> <p>Platelet-rich plasma has been advocated for treatment of chronic nonhealing wounds (e.g., chronic venous and diabetic foot ulcers) and ligament and tendon injuries (e.g., epicondylitis, tendinopathies). Platelet-rich plasma has also been combined with bone grafts during orthopedic, oral, or maxillofacial surgeries to purportedly stimulate bone formation and healing.</p> | autologous platelet-rich plasma. | |
| A-0720 | <p>Computerized Motion Analysis (Spine and Gait)</p> <p>MCG™ Care Guideline® 28th Edition</p> | Gait analysis is intended to provide measurable, reproducible assessments of ambulatory motion based on kinetic and kinematic measurements, dynamic electromyographic studies and visual recordings of motion. These data may provide useful information regarding: surgical outcomes for treatment of cerebral palsy, spina bifida and other gait disorders; treatment planning for podiatry, rehabilitative medicine and prosthetic/orthotic device design, selection and alteration. | CPT 96000, 96001, 96002, 96003, and 96004 | 12/10/2024 |
| A-0978 | Positive Pressure Therapy for Meniere Disease | Positive pressure therapy for Meniere disease uses a handheld air pressure generator placed in the external auditory canal. The device creates a series of low- | CPT Codes 69433 [†] , 69436 [†] | 12/10/2024 |

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| | MCG™ Care Guideline® 28 th Edition | pressure air pulses, which are transmitted to the inner ear vestibular system via a tympanostomy tube. Hypothetically, the air pulses influence the endolymphatic pressure within the vestibular system and mitigate symptoms of vertigo, hearing loss, and tinnitus. Patients perform the treatment on themselves; each session lasts approximately 5 minutes and is typically repeated 3 times a day. Therapy is continued indefinitely. | HCPCS Codes A4638, E2120 † When tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia (69433) or tympanostomy (requiring insertion of ventilating tube), general anesthesia (69436) is determined to be positive pressure therapy for Meniere Disease. | |
| A-1047 | Neurolysis, Genicular Nerve MCG™ Care Guideline® 28 th Edition | The genicular nerves are a group of small sensory nerves that arise from the tibial and common peroneal nerves and innervate the anterior knee. Multiple branches of the genicular nerves are described, including the superior lateral genicular nerve, superior medial genicular nerve, inferior lateral genicular nerve, and inferior medial genicular nerve, with individual variability in nerve location and depth. Inhibition of the sensory nerves to the knee joint capsule has been evaluated as a treatment for knee pain, most often involving the superior medial, inferior medial, and superior lateral genicular nerves. Nerve blockade with local anesthetic and/or a corticosteroid is sometimes used as a diagnostic procedure to select patients for a therapeutic neurolysis with chemical ablation, cryoablation, or radiofrequency ablation. The nerve targets are typically localized by fluoroscopy, ultrasound, and/or percutaneous peripheral nerve stimulation; specific targets may vary by practitioner. | CPT Code 64624 | 12/10/2024 |

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Documentation Requirements

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the service, or procedure, supply, product, or accommodation performed or furnished regardless of how the service, or procedure, supply, product, or accommodation was coded by the Provider.

Approval or clearance by the U.S. Food and Drug Administration alone is not a basis for coverage.

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Sources of Information:

- American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services. Available at: <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>. Accessed December 10, 2024.
- Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals>. Accessed December 10, 2024.
- Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets. Available at: <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>. Accessed December 10, 2024.
- Hayes, a symplr Offering. Available at: <https://www.hayesinc.com/>. Accessed December 10, 2024.
- Medical Mutual Healthcare Technology Assessment Program Description. Available at: <https://www.medmutual.com/-/media/908301A8044D420BB377375914643593.ashx>. Accessed December 11, 2024.
- National Comprehensive Cancer Network. Available at: <https://www.nccn.org/>. Accessed December 11, 2024.
- PubMed, National Library of Medicine. Available at: <https://pubmed.ncbi.nlm.nih.gov/>. Accessed December 11, 2024.
- UpToDate. Available at: <https://www.uptodate.com/>. Accessed December 10, 2024.
- U.S. Preventive Services Task Force. Available at: <https://www.uspreventiveservicestaskforce.org/uspstf/>. Accessed December 10, 2024.

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| Applicable Code(s): | |
| CPT: | See above. |
| HCPCS: | See above. |
| ICD10 Procedure Codes: | See above. |

Revised:

12/12/2024: Policy created. Policies from previous NSC list copied over.

12/19/2024: 2019-C, 200522 effective dates updated to 12/19/2024.