



**Procedures/Devices/Services** 

Policy: 202406 Effective Date: 12/19/2024

SUBJECT: Investigational/Experimental Annual Review Date: 12/12/2024

Last Revised Date: 12/19/2024

#### SERVICES IN THIS LIST OF CORPORATE MEDICAL POLICIES ARE CONSIDERED INVESTIGATIONAL/EXPERIMENTAL

**Definition:** Investigational/experimental describes a drug, medical device, treatment, or procedure that meets any of the following conditions:

- A drug or medical device cannot be lawfully marketed without clearance or approval of the U.S. Food and Drug Administration, and clearance or approval for marketing has not been given at the time the drug or device is furnished.
- Reliable evidence shows that the drug, medical device, treatment, or procedure is not considered the standard of care, is the subject of an on-going phase I, II or III clinical trial, or is under study to determine maximum tolerated dose, toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
- The consensus of opinion among experts regarding the drug, medical device, treatment, or procedure is that further studies or clinical trials are required to determine its maximum tolerated dose, toxicity, safety, or efficacy, as compared with the standard means of treatment or diagnosis.

When determining a status of investigational/experimental, 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: <a href="https://www.medmutual.com/-/media/908301A8044D420BB377375914643593.ashx">https://www.medmutual.com/-/media/908301A8044D420BB377375914643593.ashx</a>.

The American Medical Association (AMA) develops and maintains a set of temporary codes to track the utilization of emerging technologies, services, and procedures that are referenced as CPT Category III codes. The Category III code description does not establish a service or procedure as safe, effective, or applicable to the clinical practice of medicine. The AMA indicates that a Category III code will typically be archived within 5 years, and the description is either converted to a specific Category I code or should be reported with a Category I unlisted code.

**PLEASE NOTE:** The Company considers Category III codes to be investigational/experimental except when explicitly covered by a corporate medical policy (or national or local coverage determination when appropriate).

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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: <a href="https://medmutual.access.mcg.com/index.">https://medmutual.access.mcg.com/index.</a>

**Medical Necessity:** Based upon our findings, the Company has determined that the following services have not demonstrated equivalence or superiority to currently accepted standard means of treatment or standard diagnostic technique. The Company considers the following services as indicated by the Applicable Code(s) or other related code(s) not listed here **investigational** and **not** eligible for reimbursement:

| POLICY<br>NUMBER | TITLE  | DESCRIPTION  | APPLICABLE<br>CODE(S)   | EFFECTIVE/<br>REVISED<br>DATES |
|------------------|--|--|---|--------------------------------|
| 200139           | Extracorporeal<br>Shock Wave<br>Therapy for<br>Musculoskeletal<br>Conditions | Extracorporeal shock wave therapy (ESWT) is a noninvasive technique that directs low or high energy pulses to a specific painful tissue area. These pulses aim to break down calcium deposits, decrease scar tissue, and reduce inflammation, thereby decreasing pain and promoting healing at the affected site. Musculoskeletal conditions include (but are not limited to) plantar fasciitis, shoulder tendonitis, Achilles' tendinopathy, and lateral epicondylitis. | CPT Codes 28890,<br>Category III 0101T,<br>0102T, 0512T,<br>0513T   | 02/27/2025                     |
| 200224           | Sublingual<br>Immunotherapy  | Sublingual immunotherapy (SLIT) is a form of allergy treatment that utilizes repeated, sublingual placement of diluted allergen extract drops as an allergen delivery system. Gradually increased doses of the allergen are administered in an effort to achieve tolerance to the allergy-causing substance. Theoretical advantages include a lower risk of serious side effects and better patient acceptance.  | †When unlisted allergy/clinical immunologic service or procedure (95199) is determined to be sublingual (allergy) immunotherapy.  NOTE: Odactra, Grastek, Ragwitek, or Oralair may be covered, please see Drug Policy Sublingual Allergen Extract | 02/11/2025                     |

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|                  |  |  | <b>Immunotherapy</b> for more information.  |                                |
| 2003-C           | Electrical<br>Stimulation for<br>Treatment of<br>Dysphagia                             | Transcutaneous electrical stimulation (neuromuscular electrostimulation; transcutaneous electrical stimulation) of muscles coordinating swallowing is a noninvasive therapy reported to be utilized for treatment of oropharyngeal dysphagia. A hand-held electrical stimulator (e.g., VitalStim) is connected to a pair of external electrodes positioned to deliver electric current to swallowing muscles of the neck. The device provides external electrical stimulation to pharyngeal swallowing musculature in an attempt to strengthen neuromuscular pathways involved in the swallow reflex.  | CPT Codes 97014, 97032 and 97039†  HCPCS Code E0745 †When unlisted modality (specify type and time if constant attendance) (97039) is determined to be electrical stimulation for treatment of dysphagia.   | 12/19/2024                     |
| 200310           | Gastroesophage<br>al Reflux<br>Disease:<br>Endoscopic and<br>Laparoscopic<br>Therapies | Gastroesophageal reflux disease (GERD) is the chronic abnormal reflux of gastric contents into the esophagus, resulting in symptoms of heartburn and/or regurgitation. This gastric reflux may at times result in mucosal injury with esophagitis or other complications. Endoscopic and laparoscopic therapies have been developed to treat GERD; these approaches alter the gastroesophageal junction structure in order to diminish proximal migration of gastric contents and decrease reflux and regurgitation symptoms, thereby resolving esophagitis.  Endoscopic and laparoscopic therapies may be classified into four basic categories as outlined below, with some examples (NOTE: this list is not all-inclusive): | CPT 43201, 43210, 43236, 43284, 43289, 43257, 43499† and 43999†  †When unlisted procedure, esophagus (43499) or unlisted procedure, stomach (43999) is determined to be endoscopic plication/suturing for treatment of gastroesophageal reflux disease. | 04/27/2024                     |

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|                  |   | <ul> <li>Radiofrequency energy:         <ul> <li>Stretta®</li> </ul> </li> <li>Endoscopic plication/suturing             <ul></ul></li></ul>   |  |                                |
| 2005-J           | Vertebral Axial<br>Decompression<br>Devices | Vertebral axial decompression devices (e.g., VAX-D®, Accu-SPINA System, etc.) are computer-controlled tables that apply distractive tension along the spinal column. These devices are promoted as non-invasive, non-surgical procedures that treat low back pain due to conditions such as lumbar disc herniation, degenerative disc disease, posterior facet syndrome, sciatica, or radiculopathy. | HCPCS S9090  | 07/12/2024                     |
| 2006-D           | Radiofrequency<br>microtenotomy             | Radiofrequency microtenotomy (radiofrequency-based microtenotomy) is   | CPT Codes 20999 <sup>†</sup> , 23929 <sup>†</sup> , 24999 <sup>†</sup> , | 08/27/2024                     |

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| 1,01,1221        |   |   |   | DATES                 |
|                  |   | a minimally invasive procedure for treatment of chronic tendinosis. Coblation® (ArthroCare® Corporation, Austin, TX) technology, a controlled, non-heat driven process, uses radiofrequency energy in an attempt to stimulate healing by initiating an inflammatory response in damaged tissue. A damaged tendon is surgically exposed and radiofrequency energy is directly applied to the tendon surface with a TOPAZ® MicroDebrider probe (ArthroCare® Corporation, Austin, TX) at 0.5 second intervals. Radiofrequency microtenotomy has been evaluated for the treatment of chronic tendinosis refractory to conventional therapy, including the supraspinatus tendon, forearm extensor muscle aponeurosis (at lateral epicondyle), patellar tendon, Achilles tendon and plantar fascia. | 27599†, 27899† and 28899†  †When unlisted procedure- musculoskeletal system- general (20999), unlisted procedure - shoulder (23929), unlisted procedure, humerus or elbow (24999), unlisted procedure, femur or knee (27599), unlisted procedure, leg or ankle (27899) or unlisted procedure, foot or toes (28899) is determined to be radiofrequency microtenotomy for tendinosis. | DATES                 |
| 2006-G           | Fluid-Ventilated<br>Gas-Permeable<br>Scleral Lenses | Fluid-ventilated, gas-permeable scleral lenses (e.g., BostonSight PROSE device) are utilized for management of irregular corneal astigmatism that is unable to be corrected with traditional contact lenses or for treatment of diseases of the corneal surface. These devices can be custom-fitted and sized to rest largely on the surrounding sclera, creating a fluid-filled space overlying the cornea, which optically neutralizes corneal surface irregularities. The fluid-filled space protects the corneal surface from atmospheric desiccation, reduces the intensity of ocular pain and may facilitate healing of persistent epithelial defects.  | CPT 92499<br>HCPCS S0515  | 12/19/2024            |

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| 2009-C           | Anal Fistula<br>Plug   | An anal fistula plug (e.g., Biodesign® [Surgisis®] Anal Fistula Plug) is a freeze-dried bioabsorbable xenograft formulated from porcine small intestinal submucosa, which is intended as a minimally invasive treatment for anorectal or rectovaginal fistulas.  | CPT Code 46707   | 12/10/2024                     |
| 2011-C           | Wireless Gastrointestinal Motility Monitoring System -Suspected Gastric Motility Disorders | Wireless gastrointestinal motility monitoring systems (e.g., SmartPill® GI Monitoring System) have been proposed as an alternative testing method for evaluation of suspected gastrointestinal motility disorders (e.g., gastroparesis). The system senses and records temperature, pH, and pressure measurements via sensors contained within an ingestible capsule as it travels through the gastrointestinal tract. Measurements are transmitted from the capsule via a radiofrequency signal to an external data receiver and subsequently downloaded to a personal computer for analysis and review by a physician. | CPT Code 91112   | 06/12/2024                     |
| 2013-C           | Tenex Health<br>TX Procedure   | Tenex Health TX Procedure employs a minimally invasive technique intended to treat symptomatic tendon and soft tissue injuries that are unresponsive to conventional medical therapy. The procedure involves percutaneous insertion of the TX1 MicroTip™ through a 3mm incision near a tendon or soft tissue injury site (i.e., lateral or medial epicondyle, patellar tendon, rotator cuff, plantar fascia or Achilles tendon) under ultrasonic guidance. The probe ultrasonically emulsifies and removes tendon scar   | CPT Codes 20999†, 23929†, 24999†, 27599†, 27899† and 28899†  †When unlisted procedure-musculoskeletal system, general (20999), unlisted procedure, shoulder (23929), unlisted procedure, thumerus or elbow (24999), unlisted procedure, femur or knee (27599), unlisted procedure, leg or ankle (27899) or unlisted procedure, foot or toes (28899) is determined to | 12/10/2024                     |

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|                  |  | tissue, thereby reportedly alleviating tendon pain.   | be focused aspiration of scar tissue.   |                                |
| 2014-A           | Non-Surgical<br>Treatments for<br>OSA                  | Many non-surgical treatments are available for obstructive sleep apnea.  Oral pressure therapy (e.g., Attune Sleep Apnea System, iNAP One Sleep Therapy System, Winx Sleep Therapy System) involves the use of an intraoral negative pressure gradient device intended to improve airflow by increasing airway size for the treatment of obstructive sleep apnea.  Daytime neuromuscular electrical stimulation therapy is another treatment option that uses a device (e.g. eXciteOSA) to deliver electrical stimulation through a mouthpiece that is placed around the tongue. The stimulation is thought to improve tongue muscle tone and endurance to prevent upper airway collapse and obstructive sleep apnea during the night.  Devices for treatment of positional obstructive sleep apnea (POSA) can be worn around the neck or chest promting the user with soft vibrations to shift to a nonsupine position (e.g. Night Shift). | HCPCS A7002†, A7047†, E0600†, E0490, E0491, E0492, E0493, E0530  †When tubing used with suction pump, each (A7002) or oral interface used with respiratory suction pump, each (A7047) or respiratory suction pump, home model, portable or stationary, electric (E0600) is determined to be oral pressure therapy for treatment of obstructive sleep apnea. | 02/01/2025                     |
| 2016-B           | Myoelectric<br>Orthotic<br>Devices- Upper<br>Extremity | Myoelectric orthotic mobility systems (e.g., MyoPro®, Myomo e100, IpsiHand) are designed to provide limb and joint support as well as powered range of motion. These systems are intended to compensate for muscle weakness and disability resulting from cerebrovascular disease, neuromuscular disorders and  | HCPCS A9300 <sup>†</sup> ,<br>E0738, E0739,<br>E1399 <sup>†</sup> , L3904,<br>L3999 <sup>†</sup> , L7499 <sup>†</sup> ,<br>L8701, and L8702<br><sup>†</sup> When exercise equipment<br>(A9300), durable medical<br>equipment, miscellaneous   | 12/19/2024                     |

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|                  |   | injuries. Myoelectric orthotic mobility systems may help weak or paralyzed individuals to regain function and perform activities of daily living.  NOTE: The Company considers myoelectric prosthesis medically necessary when criteria are met in MCG Guideline A-0701.   | (E1399), upper limb orthosis, not otherwise specified (L3999); or upper extremity prosthesis, not otherwise specified (L7499) is determined to be myoelectric upper limb orthotic devices |                                |
| 2017-B           | Leadless Cardiac Pacemaker Systems (i.e., MicraTM Transcatheter Pacemaker System, Aveir VR Leadless System) | Leadless cardiac pacemaker systems are miniaturized, full featured single or dual chamber pacemakers that are implanted directly in the right ventricle and right atrium in the case of dual chamber pacemakers. They are thought to provide treatment options for patients with Class I or Class II indication for bradycardia pacing therapy without the increased risk for infection.  For Medicare Advantage members only: approval may be permitted if the member is participating in an FDA-approved post approval trial that is registered. | CPT Codes 33274,<br>33275, 0795T,<br>0796T, 0797T,<br>0798T, 0799T,<br>0800T, 0801T,<br>0802T, 0803T,<br>0804T, 0823T,<br>0824T, 0825T, and<br>0826T<br>HCPCS Code C1605                  | 07/01/2024                     |
| 2018-C           | Actigraphy as a<br>Standalone<br>Procedure  | Actigraphy involves monitoring motor activity with a portable device over an extended period of time. Devices include a small accelerometer that is typically worn on the wrist to record movement during sleep and may be used in a facility-based laboratory or in the home setting. Actigraphy has been proposed as a useful technique in combination with, or in place of, polysomnography to detect sleep disorders such as obstructive sleep apnea.  | CPT Code 95803  | 12/10/2024                     |

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|                  |  |  |  | DATES                 |
| 201913           | Investigational<br>Treatments for<br>Benign Prostatic<br>Hypertrophy | Benign prostatic hypertrophy (BPH) is a condition in which the prostate gland and surrounding tissues are enlarged which can impair the flow of urine from the urethra. Although not cancerous, the  | CPT codes 37241 <sup>†</sup> , 37242 <sup>†</sup> , 37243 <sup>†</sup> , 53855   | 05/11/2024            |
|                  |  | growth can cause uncomfortable urinary symptoms such as bladder, urinary and kidney problems. There are now several non-surgical treatments for BPH. These treatments are intended for men whose symptoms are refractory to medical therapy and/or who are inappropriate candidates for more invasive procedures or who do not wish to undergo these procedures. | When vascular embolization or occlusion; venous, other than hemorrhage (37241), vascular embolization or occlusion; arterial, other than hemorrhage or tumor (37242), vascular embolization or occlusion; for tumors, organ ischemia, or infarction (37243) is found to be prostatic artery embolization |                       |
|                  |  | Several treatments for benign prostatic hypertrophy, including Urolift, Rezum and Aquablation are covered procedures and are found in CMP 201913.  |  |                       |
|                  |  | Based upon our findings, the Company considers the following treatments for benign prostatic hypertrophy investigational:  |  |                       |
|                  |  | Temporary prostatic urethral stents<br>(e.g. Spanner Prostatic Stent, iTind)  Prostatic artery embolization  |  |                       |
| 2019-В           | Subchondroplast<br>y® (SCP®) with<br>AccuFill® Bone<br>Substitute    | The Subchondroplasty® Procedure (SCP®) is a minimally invasive, fluoroscopically assisted procedure in which subchondral bone defects are filled   | CPT Codes 0707T,<br>0869T, 29855 <sup>†</sup> ,<br>29856 <sup>†</sup> , 29892 <sup>†</sup>   | 04/08/2025            |
|                  | Material (BSM)   | with AccuFill® Bone Substitute Material (BSM), a calcium phosphate compound. Inside the subchondral defects AccuFill forms a hard, nanocrystalline scaffold that is replaced with new bone over time. This   | †When arthroscopically aided treatment of tibial fracture, proximal (plateau); unicondylar (29855), arthroscopically aided treatment of tibial fracture, proximal (plateau); bicondylar (29856), or  |                       |

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|                  |   | procedure is typically performed arthroscopically.   | arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture (29892), or any other code is determined to be Subchondroplasty® (SCP®) with AccuFill® Bone Substitute Material (BSM); this includes but is not limited to hips and knees. |                                |
|                  |   |  | NOTE: This list of applicable codes is not all-inclusive. The Company reserves the right to apply this policy to the procedure performed regardless of how the procedure was coded by the provider.   |                                |
| 2019-F           | Allogeneic, xenographic, synthetic, and composite nerve grafts and conduits | Peripheral nerve injuries or defects may compromise sensory and/or motor function and can profoundly impact quality of life as well as autonomy. Autologous nerve transplantation is the standard surgical treatment but has significant limitations, such as a need for a secondary surgery and an associated risk for surgical donor site morbidity. Nerve allografts comprise another approach, but some allogeneic nerve transplants may require concurrent immunosuppression. Tissue-engineered, decellularized nerve grafts and nerve conduits, as well as grafts and conduits from other sources, are intended to treat peripheral nerve injuries or defects while minimizing the potential for adverse events that are common to current treatments. | CPT Codes 64910, 64912, 64913, 64999†, HCPCS Codes C9352, C9353, C9355, C9361, Q4170  †When unlisted procedure, nervous system (CPT 64999) is determined to be allogeneic, xenographic, synthetic, or composite nerve grafts and/or conduits.   | 05/09/2024                     |

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| 2019-G           | Investigational Spinal Procedures  • Minimally invasive spinal fusion approaches using only indirect visualization (e.g. endoscopic fusion)  • Spinal fusion with a presacral interbody approach (e.g. AxiaLIF)  • Automated Percutaneous Lumbar Discectomy  • Endoscopic Disc Decompression  • Laser Disc Decompression  • Minimally Invasive Lumbar Decompression (mild®)* | There are many investigational spinal procedures that lack the clinical evidence for efficacy compared to other more standard procedures. Many of these include minimally invasive procedures for spinal fusion, discectomy and disc decompression. They are intended to increase stability of vertebral bones and joints and/or relieve any pressure being applied to the nerves and to thus alleviate chronic numbness, stiffness, and pain of the back.  NOTE: Minimally invasive spinal fusion approaches such as XLIF and DLIF, when performed with direct visualization, are approvable based on MCG criteria (S-820).  See also MCG <sup>TM</sup> Care Guideline® A-0494: Spinal Distraction Devices. | CPT 22586, 27278, 62287†, 62380†, 63020†, 63030†, 63035†, and 64999†  Category III 0274T and 0275T  HCPCS C1821, S2348  † When aspiration of nucleus pulposus of intervertebral disk, lumbar (62287), laminotomy/decompression nerve root(s); one interspace/cervical (63020), endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar (62380), laminotomy/decompression nerve root(s); one interspace, lumbar (63030); laminotomy with decompression of nerve root(s);each | 03/11/2025                     |

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|                  | <ul> <li>Nucleoplasty         Disc         Decompressio         n     </li> <li>LinQ         sacroiliac joint         stabilization         system     </li> </ul>  |   | addl. (63035); or<br>unlisted procedure,<br>nervous system<br>(64999) is determined<br>to be minimally-<br>invasive disc<br>decompression<br>procedures. |                                |
|                  | *Approval for mild® may be permitted for a Medicare Advantage member if they are enrolled in an approved clinical study that meets criteria put forth by the Centers for Medicare & Medicaid Services (CMS). This information may be available through the CMS website. |   |  |                                |
| 202009           | Dry Needling  | Dry needling, also known as intramuscular stimulation, involves the use of solid 'noninjection' needles which are used to penetrate the skin and stimulate specific triggerpoints, muscles and connective tissue. Dry needling is intended to reduce pain and improve range of motion, however more studies | CPT Codes 20560,<br>20561  | 05/16/2024                     |

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|   | are needed to demonstrate its safety and effectiveness.  |  |  |
| Microsurgical Treatments for Lymphedema – Lymphatic Bypass Procedures | Lymphedema refers to the accumulation of fluid in tissues with inadequate lymphatic drainage, which often results from breast cancer surgery, mastectomy, or radiation treatments. Microsurgical treatments for lymphedema aim to increase the capacity of the lymphatic system by creating new channels for lymphatic fluid to travel. There are several methods of lymphatic bypass, including (but not limited to) lymphovenous bypass, lymphaticovenular anastomosis, and lymphatic-capsular-venous anastomosis. | CPT Codes 15756†, 35206†, 35206†, 35226†, 35236†, 35266†, 37799†, 38308†, 38790†, 49906†, 76499†  †When free muscle or myocutaneous flap with microvascular anastomosis (15756), repair blood vessel, direct; upper extremity (35206), repair blood vessel with vein graft; upper extremity (35236), repair blood vessel with vein graft; upper extremity (36266), unlisted procedure, vascular surgery (37799), lymphangiotomy or other operations on lymphatic channels (38308), unlisted procedure, hemic or lymphatic system (38999), free omental flap with microvascular anastomosis (49906), or unlisted diagnostic radiographic procedure (76499) is determined to be microsurgical treatments for lymphedema. | 05/16/2024   |
| Irreversible<br>Electroporation<br>(IRE)                              | Irreversible electroporation (IRE) is a nonthermal ablative technique that induces cell death by directly delivering multiple pulses of high-voltage electrical current to a targeted area. The electrical current permanently changes cell permeability by causing tiny holes to open in the cell membrane. This technique  | CPT Codes 0600T,<br>0601T, 47399†<br>ICD 10 Procedure<br>Codes 0F500ZF-<br>0F504ZF, 0F510ZF-<br>0F514ZF, 0F520ZF-<br>0F524ZF, 0F5G0ZF-   | 09/03/2024   |
|   | Lymphatic Bypass Procedures  Irreversible Electroporation  | Treatments for Lymphedema – Lymphatic Bypass Procedures  Irreversible Electroporation (IRE)  Irreversible Electroporation (IRE) is a nonthermal ablative technique that induces cell death by directly delivering multiple pulses of high-voltage electrical current to a targeted area. The electrical current permanently changes cell permeability by causing tiny holes to open  | Treatments for Lymphedema – Lymphatic drainage, which often results from breast cancer surgery, mastectomy, or radiation treatments. Microsurgical treatments for lymphedema aim to increase the capacity of the lymphatic system by creating new channels for lymphatic fluid to travel. There are several methods of lymphatic bypass, including (but not limited to) lymphovenous bypass, lymphatic-capsular-venous anastomosis.    When free muscle or myocutaneous flap with microvascular anastomosis (15756), repair blood vessel, direct; toper extremity (35236), repair blood vessel with graft other than vein; upper extremity (3626), sunlisted procedure, family conceuter (37799), lymphangiotomy or other operations on lymphatic channels (38308), unlisted procedure, lemic or lymphatic system (3899), free omental flap with microvascular anastomosis (49906), or unlisted diagnostic radiographic procedure (38799) is determined to be microsurgical treatments for lymphedema.    Irreversible   Electroporation (IRE)   Elect |

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|                  |  | causing less damage to surrounding tissues than with thermal ablative techniques  | †When <i>unlisted procedure</i> ,<br><i>liver</i> (47399) is determined to<br>be irreversible electroporation |                                |
| 202016           | Cryotherapy or radiofrequency therapy ablation for Allergic and Non-Allergic Rhinitis (ClariFix and RhinAer) | Cryoablation involves the use of extreme cold to destroy tissue. The ClariFix device is a hand-held, disposable device used to destroy tissue during surgical procedures, including in adults with chronic allergic and non-allergic rhinitis.  Radiofrequency ablation involves the use of heat generated by radiofrequency waves to destroy tissue. RhinAer uses low temperature energy to ablate the nerve that causes chronic allergic and non-allergic rhinitis. | CPT Codes 31242, 31243  | 10/08/2024                     |
| 202202           | Peripheral<br>Electrical<br>Stimulation to<br>Reduce Tremor<br>(e.g. Cala Trio)                              | Cala Trio is a devise worn on the wrist that provides non-invasive electrical stimulation to the median and radial nerves. This type of stimulation therapy is called transcutaneous afferent patterned stimulation (TAPS) and is intended to reduce tremor in the targeted arm.  | HCPCS Codes<br>A4542, E0734   | 09/07/2024                     |
| 202203           | Non- pneumatic compression devices   | Non-pneumatic compression devices (e.g., Koya Dayspring System) are wearable systems that provide sequential gradient compression for the treatment and management of lymphedema. These devices are intended to promote lymph flow while allowing patients to maintain mobility during treatment.   | HCPCS Codes<br>E0677, E0678,<br>E0679, E0680,<br>E0681, E0682,<br>E0683                                       | 12/10/2024                     |
| 202204           | Intravascular<br>Lithotripsy<br>(IVL)  | Intravascular lithotripsy (IVL) is a procedure used to open narrow or blocked coronary or peripheral arteries due to calcification prior to stent implantation. The procedure is administered with a  | CPT Code 92972 and<br>HCPCS Codes<br>C9764, C9765,<br>C9766, C9767,<br>C9772, C9773,                          | 02/11/2025                     |

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|                  |  | device (e.g. Shockwave Intravascular<br>Lithotripsy System) that consists of a<br>catheter which delivers localized pressure<br>waves to the lesion. These pressure waves<br>are intended to break up the calcification<br>that is restricting blood flow.  | C9774, C9775,<br>C1761  |                                |
| 202205           | Cardiac<br>Contractility<br>Modulation<br>Therapy                    | Cardiac Contractility Modulation (CCM) therapy (e.g. Optimizer Smart System, Impulse Dynamics) is a proposed treatment for heart failure in patients who are not eligible for cardiac resynchronization therapy. It involves the implantation of a pulse generator into the right pectoral region of the heart. The generator then delivers CCM signals, which are biphasic and relatively high voltage, to the right ventricular septum which is thought to increase the contractile strength of cardiac muscle. | CPT Codes 0408T,<br>0409T, 0410T,<br>0411T, 0412T,<br>0413T, 0414T,<br>0415T, 0416T,<br>0417T, 0418T<br>HCPCS Code K1030  | 04/05/2024                     |
| 202304           | Arthroscopy-<br>Shoulder-<br>Surgical<br>subacromial<br>spacer       | Subacromial- balloon spacer (InSpace – Stryker) is a biodegradable implant designed to restore the subacromial space in rotator cuff injury. This is reported to be a less invasive solution compared to other surgical treatment options that require fixation devices or grafts in the presence of rotator cuff injury, includes debridement (e.g., limited, or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed.  | HCPCS Code C9781  | 02/11/2025                     |
| 202501           | Medial Knee<br>Implanted<br>Shock Absorber<br>(MISHA Knee<br>System) | The MISHA Knee System (Moximed Inc.) is an implantable shock absorber that is intended to treat knee osteoarthritis. The MISHA consists of an implant that is placed outside of the knee joint, where it is connected to the proximal tibia and distal femur. The implant is designed to  | CPT Code 27599† HCPCS Code C1776†  †When 27599 (unlisted procedure, femur or knee) or C1776 (joint device (implantable)) is found to be medial knee implanted shock absorber. | 02/11/2025                     |

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|                  |   | offload the medial knee joint while supporting natural movement.  |   |                                |
| A-0242           | Electromagnetic<br>Therapy<br>MCG <sup>™</sup> Care<br>Guideline <sup>®</sup> 28 <sup>th</sup><br>Edition                 | Pulsed electromagnetic field therapy is a noninvasive, adjunctive therapy utilized to accelerate improvement and stimulate healing in chronic, nonhealing dermal ulcers unresponsive to conventional wound therapy.   | HCPCS E0761,<br>E0769, G0295,<br>G0329                  | 12/10/2024                     |
| A-0289           | MRI-Guided<br>Focused<br>Ultrasound<br>Surgery, Uterus<br>MCG <sup>™</sup> Care<br>Guideline® 28 <sup>th</sup><br>Edition | Magnetic resonance imaging-guided high-<br>intensity focused ultrasound ablation is a<br>noninvasive procedure developed to ablate<br>uterine fibroid tissue.   | CPT Codes 0071T,<br>0072T                               | 12/10/2024                     |
| A-0494           | Spinal Distraction Devices  MCG <sup>™</sup> Care Guideline® 28 <sup>th</sup> Edition                                     | Interspinous distraction devices, such as the Wallis, X-Stop, Coflex, DIAM, Aperius, and Superion devices, are spacers placed between vertebral levels to limit extension without affecting flexion, axial rotation, or lateral bending. They reduce intradiskal pressure and facet load, and they prevent narrowing of the spinal canal and neural foramen. Proposed applications include relief of discogenic low back pain and neurogenic claudication due to spinal stenosis. | CPT Codes 22867,<br>22868, 22869, 22870<br>HCPCS: C1821 | 12/10/2024                     |
| A-0567           | Ovarian and Internal Iliac Vein Embolization  MCG <sup>™</sup> Care Guideline® 28 <sup>th</sup> Edition                   | Pelvic congestion syndrome (PCS) is characterized by chronic pelvic pain that is unexplained by other etiologies. PCS may develop due to varicosities and/or valvular incompetence within the pelvic veins.  Embolization of the ovarian vein and/or internal iliac vein is a treatment approach that involves the use of embolic agents to   | CPT Codes 37241,<br>75894, 75898                        | 12/10/2024                     |

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|                  |  | reroute blood flow, aiming to reduce pressure within the targeted veins.  |  |                                |
| A-0578           | Migraine Headache, Surgical Treatment  MCG <sup>™</sup> Care Guideline® 28 <sup>th</sup> Edition | Migraine, cluster and other headache syndromes are common, often debilitating, primary headache disorders. Surgical interventions have been proposed for the prevention, reduction or elimination of these headache types. Similar therapies have been proposed for tension-type headaches and occipital neuralgia. Examples of these procedures include: resection or manipulation of facial muscles or soft tissue from the forehead, periorbital, occipital or other facial or scalp areas; resection of the trigeminal nerve or its branches; surgical modification of the sinuses; and patent foramen ovale closure. | CPT Codes 15824,<br>15826, 21299, 30130,<br>30140, 30520, 30801,<br>30802, 31200, 31201,<br>31205, 31254, 31255,<br>64732, 64734, 64744,<br>67900, 93580<br>(or any codes found<br>to be for services<br>listed) | 12/10/2024                     |
| A-0634           | Bronchial<br>Thermoplasty<br>MCG <sup>™</sup> Care<br>Guideline® 28 <sup>th</sup><br>Edition     | Bronchial thermoplasty (Alair® Bronchial Thermoplasty System, Boston Scientific, Sunnyvale, CA) is a procedure purported to weaken and partially destroy the airway smooth muscle responsible for the bronchoconstriction associated with asthma attacks. A course of bronchial thermoplasty usually consists of several treatment sessions performed under moderate sedation by a pulmonologist for adults with severe persistent asthma that has not been well controlled by conventional medical therapy, including optimal doses of long-acting bronchodilators and glucocorticoids.                                  | CPT Codes 31660<br>and 31661   | 12/10/2024                     |
| A-0667           | Bioimpedance<br>Spectroscopy   | Bioimpedance spectroscopy (BIS) is a noninvasive technique utilized in the measurement of extracellular fluid   | CPT Codes 0358T,<br>93702  | 12/10/2024                     |

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|                  | MCG <sup>™</sup> Care<br>Guideline <sup>®</sup> 28 <sup>th</sup><br>Edition   | volume differences between the arms and has been reported to aid in detection of unilateral arm lymphedema in women. A small electrical current is passed through electrodes attached to the wrists to measure resistance (impedance) to current. A device is utilized to record impedance at varying frequencies (e.g., ImpediMED L-Dex U400 BIS Extra Cellular Fluid Analyzer, ImpediMed Limited, Queensland Australia; San Diego, CA). Results are analyzed to determine if more fluid exists as compared to the contralateral limb. This technique has been proposed as an alternative to circumferential measurements and water immersion methods to indicate trends toward the potential development of lymphedema. |   |                                |
| A-0718           | Radiofrequency Ablation of Tumor  - Benign thyroid nodules  MCG <sup>™</sup> Care Guideline® 28 <sup>th</sup> Edition | Radiofrequency ablation (RFA) uses high frequency alternating current to induce thermal injury and cell death in a targeted area of tissue. It may be performed percutaneously or surgically via laparoscopy or laparotomy, and CT, MRI, or ultrasound may be used for guidance. For RFA of benign thyroid nodules, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended.  | CPT Codes 20982 <sup>†</sup> , 32998 <sup>†</sup> , 47370 <sup>†</sup> , 47380 <sup>†</sup> , 47382 <sup>†</sup> , 50592 <sup>†</sup> , 58674 <sup>†</sup> HCPCS Code C1886 <sup>†</sup> <sup>†</sup> When codes listed above are used to describe radiofrequency ablation of benign thyroid nodules. | 12/10/2024                     |
| A-0727           | Intrapulmonary<br>Percussive<br>Ventilation<br>(IPV)  | Intrapulmonary percussive ventilation (IPV) is a breathing system that attempts to loosen mucus by internally percussing the airways through the delivery of high-frequency, high-flow, low-pressure bursts of gas in an oscillating fashion to a   | HCPCS Code E0481  | 12/10/2024                     |

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|                  | MCG <sup>™</sup> Care<br>Guideline® 28 <sup>th</sup><br>Edition   | spontaneously breathing patient via mask, mouthpiece, or tracheostomy; it is most commonly used in patients on mechanical ventilation. Aerosolized bronchodilators or other medications can be delivered in these bursts of gas. Airway clearance is thought to result from improved lung expansion and creation of vibrations within the airways that loosen mucus and secretions.   |  |                                |
| A-0998           | Vagus Nerve Stimulation, Transcutaneous  MCG <sup>™</sup> Care Guideline® 28 <sup>th</sup> Edition                                | A transcutaneous vagus nerve stimulator is a portable, battery-powered device that is either placed directly on the skin of the neck or connected to an electrode that is placed in the left ear. Preprogrammed, intermittent electrical pulses are transmitted to the brain via the various branches of the vagus nerve.   | †When durable medical equipment, miscellaneous (E1399) is used to describe transcutaneous vagus nerve stimulation. | 12/10/2024                     |
| A-1025           | Saphenous Vein Ablation, Mechanical Occlusion Chemical Ablation (MOCA)  MCG <sup>™</sup> Care Guideline® 28 <sup>th</sup> Edition | Mechanical occlusion chemical ablation (MOCA) of the saphenous vein is a nonthermal technique that combines mechanical epithelial injury via a catheter-directed rotating wire with concomitant chemical ablation via simultaneous administration of a sclerosing agent (e.g., sodium tetradecyl sulfate, polidocanol) over the rotating wire. Ultrasonography is used to continuously guide the procedure. For saphenous vein incompetence, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. | CPT Codes 36473, 36474   | 12/10/2024                     |
| A-1050           | EEG,<br>Quantitative  | A quantitative electroencephalogram (qEEG) involves the recording and processing of EEG signals to yield a visual (topographic) representation of   | CPT Codes 95812 <sup>†</sup> , 95813 <sup>†</sup> , 95816 <sup>†</sup> , 95957 <sup>†</sup> ,                      | 12/10/2024                     |

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|                  | (Brain<br>Mapping)<br>MCG <sup>™</sup> Care<br>Guideline® 28 <sup>th</sup><br>Edition           | EEG-derived data mapped across the brain. The data derived from qEEG can be used to assess cortical connectivity, coherence, ratio, power, and distribution.   | 95961 <sup>†</sup> , 95962 <sup>†</sup> , 95999 <sup>†</sup> HCPCS Code S8040 <sup>†</sup> When codes listed above are used to describe quantitative electroencephalogram.   |                                |
| B-821-T          | Vagus Nerve Stimulation, Implantable: Behavioral Health Care  MCG™ Care Guideline® 28th Edition | Vagus nerve stimulation (VNS) involves the use of a pulse generator which is implanted subcutaneously within the chest wall. Thin, flexible wires are tunneled beneath the skin to the lower neck region and attached to the left vagus nerve. Preprogrammed, intermittent electrical pulses are transmitted to the brain via the vagus nerve. | CPT Codes 61885 <sup>†</sup> , 61888 <sup>†</sup> , 64553 <sup>†</sup> , 64568 <sup>†</sup> , 64569 <sup>†</sup> , 64570 <sup>†</sup> , 95970 <sup>†</sup> , 95976 <sup>†</sup> , 95977 <sup>†</sup> HCPCS Codes C1767 <sup>†</sup> , C1778 <sup>†</sup> , C1820 <sup>†</sup> , C1826 <sup>†</sup> , C1827 <sup>†</sup> , L8679 <sup>†</sup> , L8680 <sup>†</sup> , L8685 <sup>†</sup> , L8686 <sup>†</sup> , L8687 <sup>†</sup> , L8688 <sup>†</sup> <sup>†</sup> When these codes are used to describe vagus nerve stimulation for behavioral health conditions. | 12/10/2024                     |

#### **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.

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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:**

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| <b>Applicable Code(s):</b> |            |
|----------------------------|------------|
| CPT:                       | See above. |
| HCPCS:                     | See above. |
| ICD10 Procedure Codes:     | See above. |

#### **Revised:**

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

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