

Experimental, Investigational, or Unproven

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Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Introduction

Items currently considered experimental, investigational, or unproven include, but are not limited to, the following:

- Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (HCPCS A4540)
- Neuromodulation stimulator system, adjunct to rehabilitation therapy regime (HCPCS A4593)
- Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each (HCPCS A4594)
- Cranial electrical stimulation (cranial electrotherapy stimulation) (HCPCS E0732, A4596)
- Transcutaneous tibial nerve stimulator (HCPCS E0736)
- Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month (HCPCS A4543)
- Electrode for external lower extremity nerve stimulator for restless legs syndrome (HCPCS A544)
- External lower extremity nerve stimulator for restless legs syndrome, each (HCPCS E0743)
- Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month (HCPCS A4545)
- Transcutaneous electrical nerve stimulator for nerves in the auricular region (HCPCS E0721)

- Transcutaneous electrical acupoint stimulation (TEAS) (HCPCS E0765)
- Transcutaneous tibial nerve stimulator, controlled by phone application (HCPCS E0737)
- Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories (HCPCS E0738)
- Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors (HCPCS E0739)
- Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (HCPCS E0469)
- Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter) (HCPCS A7021)
- Non-pneumatic, non-sequential, peristaltic wave compression pump (HCPCS E0683)
- Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories (HCPCS E0767)
- Apos® customized biomechanical footwear device (HCPCS E1399)
- Jaw motion rehabilitation system (HCPCS E1700)
- Replacement cushions for jaw motion rehabilitation system (HCPCS E1701)
- Replacement measuring scales for jaw motion rehabilitation system (HCPCS E1702)
- Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only (HCPCS E3200)
- Intent decoding module or pattern recognition add-on module for an upper limb myoelectric prosthetic device (HCPCS L6700)
- Myoelectric and/or power enhanced upper extremity orthotic device (HCPCS L8701, L8702)
- Magnetic shoe inserts (i.e. orthosis with magnetic foil)
- Foot adductus positioning device for the treatment of metatarsus adductus (HCPCS L3649)
- Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated (HCPCS L2006)
- Electronic transanal irrigation system, includes electronic pump, water reservoir, tubing, and accessories, without catheter, any type (HCPCS A4479)
- Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted (HCPCS A8005)

- Powered, cable driven assist glove, hand, finger, includes pressure sensors, glove replacement only (HCPCS A8006)
- Addition to lower extremity orthosis, ankle system, microprocessor-controlled feature plantarflexion and/or dorsiflexion, includes power source (HCPCS L2221)
- External ocular negative pressure pump, electric (HCPCS E2403)
- Supplies and accessories for use with an external ocular negative pressure pump, any type, per month (HCPCS A6614)

Criteria

Experimental, Investigational, or Unproven

See EviCore's Guideline Definitions under Supplemental Content at www.evicore.com"

Evidence Discussion

HCPCS A4540: Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm

A distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (remote electrical neuromodulation (REN) device) is used for the acute treatment of migraine. The mechanism of action involves electrical stimulation applied to peripheral nerves in the upper arm to induce conditioned pain modulation. The device is affixed to the individual's arm and is operated using a smartphone application.

Nerivio™ (Theranica Bio-Electronics Ltd., Israel) is a Food and Drug Administration's (FDA)-approved wireless REN device indicated for individuals 12 years of age or older for acute treatment of episodic or chronic migraine. According to the Medicare Benefit Category and Payment Determination for Nerivio™ (CMS, 2022), Nerivio™ can support 12 treatments of 45 minutes, or 540 minutes, for up to an 18-month period. Per the Nerivio™ user manual, once treatments have been completed, the device should be disposed of.

Yarnitsky et al. (2019) conducted a randomized controlled trial (n= 252) to examine the safety and efficacy of a REN device compared to a sham device for the acute treatment of migraine. A smartphone-controlled wireless REN device was applied for 30-45 minutes on the upper arm within one hour of migraine attack onset. Migraine pain levels and most bothersome symptoms (MBS) were recorded at baseline, two, and 48 hours post-treatment. Individuals receiving active stimulation achieved more pain relief, which was sustained 48 hours post-treatment. The incidence of device-related adverse events was low and similar between treatment groups. The

authors concluded that REN is an effective acute migraine treatment with a favorable safety and tolerability profile. However, the authors noted several drawbacks to the study, including a low rate of severe baseline pain intensity and high rate of mild pain intensity, a lack of reported efficacy of the device at intervention periods over one hour of symptom onset, and the difficulty of selecting an appropriate sham device for successful blinding.

Tepper et al. (2023) conducted a randomized controlled trial (n=179) that evaluated the use of REN for the prevention of migraine. Participants used either a REN device or a sham device every other day for an eight-week intervention period. Participants reported their symptoms daily via an electronic diary. REN was superior in the change in mean number of episodic and chronic migraine days per month from baseline, percentage of individuals achieving 50% reduction in moderate/severe headache days, and reduction in days of acute medication intake. No serious device-related adverse events were reported in any group. The authors concluded that when used every other day, REN is effective and safe for the prevention of migraine headache.

Grosberg et al. (2021) conducted an open-label, single-arm study including 91 individuals to evaluate pain relief, improvement of symptoms, and functional disability during a four-week trial using a REN device. Participants used an electronic diary to record symptoms at treatment initiation, two hours after treatment, and 24 hours after treatment. Pain relief and pain disappearance at two hours were achieved by 59.3% (54/91) and 20.9% (19/91), and sustained pain relief at 24 hours was observed in 64.4% (29/45) of those who achieved pain relief at two hours. The investigators concluded that REN may provide a non-pharmacological acute treatment option in individuals with chronic migraine. The authors reported several limitations to the study including a lack of a sham stimulation group, small number of subjects included in the study, and a reported nonadherence with study protocol. The authors noted that additional studies with a larger number of subjects are needed.

HCPCS E0721, E0765, A4543: Transcutaneous auricular neurostimulation (tAN) (e.g., Sparrow Ascent®) , Transcutaneous electrical acupoint stimulation (TEAS), Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month

A transcutaneous auricular neurostimulation (tAN) device (Sparrow Ascent) is intended to provide non-invasive, transcutaneous stimulation of the nerves on and/or around the auricle (ear). This device has been proposed to aid in the reduction of opioid withdrawal symptoms when used in conjunction with standard treatments for opioid use disorder in adult individuals.

In 2021, the FDA cleared the Sparrow Therapy System (Spark Biomedical, Inc., San Diego, CA), a transcutaneous auricular nerve field stimulation device, via the 510(k)

premarket approval process as a Class II device. The Sparrow Therapy System FDA submission cited the NSS-2 Bridge as the predicate device, the difference being that the NSS-2 Bridge device delivers stimulation percutaneously, versus transcutaneously with the Sparrow device. The newer Sparrow Ascent device was cleared by the FDA in 2023, with identical functioning and indications for use.

Tirado et al. (2022) conducted a randomized, sham controlled inpatient study followed by a five day open label period (n=31) and found that tAN (Sparrow device) significantly reduced Clinical Opiate Withdrawal Scale (COWS) scores versus sham during the blinded period; and thus, was judged as overall safe and effective. The authors noted multiple study limitations, including a small sample size.

Transcutaneous electrical acupoint stimulation (TEAS), also called electrical acustimulation and transdermal neuromodulation, involves placing surface electrodes on the skin to deliver an electrical current to specific acupoints on the body.

Ma et al. (2024) conducted a randomized controlled trial (n=120) to evaluate the efficacy and safety of TEAS on individuals with mild hypertension, comparing 2 Hz and 10 Hz to investigate optimal frequency. The TEAS group received 30-minute sessions for 4 weeks, three times a week. The primary outcome was the change in mean systolic blood pressure (SBP) in week 4 from baseline. The reduction in SBP was greater in the TEAS 10 Hz group than in the 2 Hz group ($p = 0.001$). However, at both frequencies, individuals saw a reduction in SBP. No adverse effects were reported.

A 2024 systematic review and meta-analysis by Yeh et al. involving a total of 33 studies (n=207) found that in individuals with chemotherapy-induced peripheral neuropathy (CIPN) symptoms, TEAS was the second most effective intervention for alleviating those symptoms, following acupuncture. There were no adverse effects reported when using TEAS. Evidence also suggested that TEAS activated opioid receptors, playing a role in pain reduction. Additionally, the review found that TEAS positively influences motor nerve conduction velocity.

A 2025 umbrella review of 14 systematic reviews conducted by Yeh et al. found that TEAS effectively alleviated CIPN symptoms, reduced CIPN pain, and enhanced quality of life. Furthermore, TEAS was associated with minimal adverse effects, making it a safe adjunctive therapy.

A 2025 review by Cocores et al. provided an updated overview on neuromodulation for migraine and other primary headache disorders, emphasizing recent advances and emerging indications. Non-invasive neuromodulation devices, such as external trigeminal transcutaneous electrical nerve stimulation (TENS), single-pulse transcranial magnetic stimulation (sTMS), and remote electrical neuromodulation (REN), are FDA-cleared for migraine management. Clinical trials demonstrate these devices are generally safe, well-tolerated, and effective for acute and preventive treatment. For

example, REN significantly reduced monthly migraine days in both episodic ($p=0.003$) and chronic migraine ($p=0.001$).

HPCPS A4593, A4594: Neuromodulation stimulator system, Adjunct to rehabilitation therapy regime

A neuromodulation stimulator system (i.e., Portable Neuromodulation Stimulator (PoNS®) (Helius Medical Inc.)) describes a translingual, non-implantable tongue stimulator intended for use as a short-term adjunct to a supervised therapeutic exercise program for the treatment of a gait deficit due to mild to moderate symptoms of multiple sclerosis (MS) in individuals 22 years of age and over. The device provides therapy through a controller and a mouth piece. The controller (HPCPS A4593) generates the delivery of electrotactile stimulation to the trigeminal and facial nerves through the mouthpiece (HPCPS A4594) while the individual is performing prescribed therapeutic exercises to directly activate brainstem areas and trigger neuroplastic changes in the brain (cerebral cortex) over a 14-week therapeutic period. PoNS received the Food and Drug Administration's (FDA's) De Novo clearance in March 2021 (US FDA, 2021) indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms from MS.

Tyler et al. (2014) conducted a randomized trial ($n=20$) with chronic MS and gait disturbance to examine the effect of targeted physical therapy with and without cranial nerve non-invasive neuromodulation (CN-NINM). The primary outcome measure was the Dynamic Gait Index (DGI) where the clinician scored an index of eight gait tasks. The results showed that the PoNS® group on average achieved improvement in their DGI score of 7.95 at the end of the study, which was statistically significant and clinically significant, compared to the control group. The authors concluded that tongue-based neurostimulation may amplify the benefits of exercise for improving gait in people with chronic MS. However, the investigators noted that the sample size was small, and further studies are warranted to determine the efficacy of this intervention.

Boughen et al. (2022) conducted a systematic review of 40 studies including individuals with traumatic brain injury, multiple sclerosis, Parkinson's disease and spinal cord injury who used CN-NINM via translingual nerve stimulation (TLNS). Most studies used the PoNS® device in conjunction with a rehabilitation program to improve functional outcomes such as balance and gait. The authors concluded that the findings suggest that TLNS is a feasible modality that can be incorporated into home-based programs. However, further research on which populations, including clinical indicators, is indicated for TLNS and the optimal parameters are required.

HPCPS E0732, A4596: Cranial electrotherapy stimulation (CES) system

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, is a non-invasive form of neurostimulation that uses a battery-operated device to deliver low voltage, alternating current to the brain via electrodes attached to the scalp or infra- or supra-auricular structures (e.g., earlobes, mastoid processes, zygomatic arches, or maxilla-occipital junctions). CES has been evaluated for the treatment of a variety of conditions, including but not limited to anxiety, depression, insomnia, pain, fibromyalgia, and opiate withdrawal. The mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system.

Per FDA regulations, CES devices should only be available to individuals when prescribed by licensed medical practitioners. Some Class II CES devices available to treat anxiety and insomnia in the United States as of early 2024 include Alpha-Stim AID (Electromedical Products International, Inc.), Alpha-Stim M (Electromedical Products International, Inc.), and CES Ultra (Neuro-Fitness, LLC).

A single-arm pilot study conducted by Chu et al. (2024) assessed a six-week CES treatment (Alpha-Stim AID) for late-life generalized anxiety disorder (GAD) (n=27). Anxiety severity, measured by the Hamilton Anxiety Rating Scale (HAM-A), significantly decreased from baseline to week six ($p \leq 0.001$) and remained improved at week 10 follow-up ($p < 0.001$). Secondary outcomes showed significant reductions in depressive symptoms and improved sleep quality at week six ($p \leq 0.05$). All adverse effects were mild and self-limiting. These findings suggest CES may be a safe and effective adjunctive therapy for reducing anxiety and depression and improving sleep in late-life GAD, warranting further randomized controlled trials.

A randomized controlled trial conducted by Ravari et al. (2024) examined the effect CES on depression, anxiety, and drug craving in 60 male participants undergoing methadone maintenance treatment. Participants were randomized into CES treatment and placebo groups for 8 weeks (48 sessions, 30 minutes each). Before the intervention, there were no significant differences between groups in depression, anxiety, or craving scores ($p \geq 0.05$). After the intervention, depression and anxiety scores were lower in the CES group compared to placebo, but these differences were not statistically significant ($p = 0.26$ and $p = 0.12$, respectively). However, drug craving was significantly reduced in the CES group ($p \leq 0.01$). No adverse effects were reported. Overall, CES did not significantly outperform placebo for depression and anxiety but was effective in reducing drug craving, suggesting its potential as an adjunctive therapy for relapse prevention.

Chung et al. (2023) performed a meta-analysis including eight randomized controlled trials (n=337) to examine the therapeutic effects of CES in individuals with anxiety,

depressive, and insomnia symptoms. The authors concluded that the therapeutic effectiveness of CES for symptoms of anxiety, depression, and insomnia in individuals with anxiety using the Alpha-Stim device was better in the CES group than in the control group.

Lee et al. (2023) conducted a randomized controlled study (n=62) with depression to investigate the effectiveness of CES in reducing stress. The intervention group used the device for 30 minutes twice a day for three weeks. After the intervention, the depression rating scales (measured via the Beck depression inventory-II) significantly improved in the CES group compared to the sham group. In addition, the stress response (measured by quantitative electroencephalography and serial salivary cortisol levels) significantly improved in the CES group compared to the sham group. Thus, the investigators concluded that CES may alleviate depressive symptoms and stress response; however, the authors noted that bias may have been introduced during the process because device use and sample collection were self-conducted by participants at home.

HPCPS E0736, E0737: Transcutaneous Tibial Nerve Stimulator, Transcutaneous tibial nerve stimulator, controlled by phone application

A transcutaneous tibial nerve stimulator (TTNS) is a device designed to deliver non-invasive transcutaneous electrical stimulation of the posterior tibial nerve. The device is used for the treatment of overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Percutaneous tibial nerve stimulation (PTNS) can be used to treat OAB and fecal incontinence. PTNS was approved by the FDA for treatment of OAB in 2000. However, a notable limitation of PTNS is its invasive nature, requiring individuals to present to a physician's office or clinic for treatment. Transcutaneous tibial nerve stimulation (TTNS) is a non-invasive alternative using electrodes placed on the skin. GEKO (Firstkind) was originally approved by the FDA in 2019 for prevention of deep vein thrombosis (DVT) after a stroke (Firstkind Ltd, 2019). It is now being studied for use in treating OAB and fecal incontinence in the home setting (Al-Danakh et al., 2022).

ZIDA® Wearable Neuromodulation System is an FDA-approved device indicated for the treatment of OAB and the associated symptoms. ZIDA® Wearable Neuromodulation System utilizes sock-based, non-invasive transcutaneous contacts that deliver a neuromodulation signal through the skin to the posterior tibial nerve.

Cava and Orlin (2022) conducted a prospective, blinded, randomized controlled trial (n=40) with OAB. The study included a treatment group which used an active ZIDA® activation device utilizing Transcutaneous tibial nerve stimulation (TTNS) and a sham control group. Both groups self-administered the treatment once weekly for 30 minutes at home for 12 weeks. The ZIDA® group reported an 80% success

rate in treated symptoms of overactive bladder with a 71% reduction in episodes of incontinence and 62% reduction in episodes of urinary urgency.

A systematic review and meta-analysis (Vaca-Benavides et al., 2025) evaluated the impact of electrical parameters in TTNS for treating OAB. Forty-two studies were included (n=2715). TTNS protocols varied, with most using 10 Hz or 20 Hz frequency. Meta-analysis of eight RCTs showed TTNS significantly reduced urinary incontinence episodes compared to control with indications that there was greater benefit at 10 Hz versus little or no effect at 20 Hz (($p = .04$)). TTNS also improved urgency overall a possible effect at 10 Hz, but not at 20 Hz. No significant improvement was observed for urinary frequency. No serious adverse events were reported. Overall, TTNS appeared safe and effective for reducing incontinence and urgency, with evidence suggesting that the 10 Hz frequency may optimize outcomes. Certainty of evidence ranged from moderate to high, but heterogeneity and limited data warrant further research.

Ghavidel-Sardsahra et al. (2022) conducted a systematic review of nine studies including 11 trials to compare the safety and efficacy of PTNS and TTNS and found that when PTNS or TTNS were compared to sham, placebo, no treatment, or conservative management, a decrease in frequency of urination was observed in both PTNS and TTNS. The authors concluded that nerve stimulations with either PTNS or TTNS appear to be effective interventions in treating refractory idiopathic OAB in terms of daily voiding frequency, maximum voided volume (MVV), urgency episodes, and nighttime voiding frequency. However, the results did not show any improvement in terms of urinary incontinence, post-void residual volume, urge incontinence, or maximum cystometric capacity.

Aydogmus et al. (2025) evaluated the effectiveness of eight weeks of TTNS versus sham therapy in 56 women with OAB. Participants received weekly sessions for eight weeks and were followed for 12 months. After treatment, the TTNS group showed better outcomes than the sham group in Overactive Bladder Questionnaire Awareness tool V8 (OAB-v8) scores (14.2 vs. 26.6), International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) scores (7.4 vs. 14.4), and Visual Analog scale (VAS) scores (4.2 vs. 8.4), all $p < 0.05$. Quality of life improved markedly in the TTNS group, with scores increasing from 42.1 pre-treatment to 85.7 at 3 months ($p = 0.001$) and 68.5 at 6 months ($p = 0.001$), but declined to 49.8 at 12 months ($p = 0.51$). Bladder diary data showed reductions in daily frequency (65.7%), nocturia (70.8%), and urgency episodes (69.2%). No adverse effects were reported. Overall, TTNS significantly improved OAB symptoms and quality of life in the short and mid-term, but its long-term effectiveness diminished, suggesting that repeat sessions every 6–8 months may be necessary for sustained benefit.

A multicenter, double-blind randomized controlled trial conducted by Zhang et al. (2025) evaluated the efficacy and safety of a non-invasive low-frequency tibial nerve stimulator versus sham treatment in 109 adults with OAB. Participants received three 30-minute sessions per week for 12 weeks. The primary outcome, change in Overactive Bladder Symptom Score (OABSS) at week 12, was significantly greater in the TTNS group compared to sham ($p = 0.02$). At week 8, the TTNS group showed significantly greater improvement in absolute and percent changes of average daily urge urinary incontinence (UUI) episodes compared to sham ($p = 0.01$). Other secondary outcomes (including nocturia, urinary frequency, urgency episodes, single voided volume, and quality of life) did not differ significantly between groups (all $p > 0.05$). Analysis revealed no serious adverse events; one mild hematuria occurred in the sham group. Overall, TTNS demonstrated short-term efficacy in reducing OAB symptoms and was well tolerated, though most secondary outcomes showed similar improvements in both groups, suggesting a strong placebo effect.

HPCPS E0738: IpsiHand™ Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories

An upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories is a powered upper extremity rehabilitation system that consists of a biometric electroencephalogram (EEG) headset for use of the unaffected hemisphere, a powered upper extremity range of motion assist device, and a microprocessor control unit containing therapy software. The device detects electrical activity with electroencephalography and uses that information to drive an orthotic handpiece (motorized glove), allowing the individual to engage in voluntary grasping movements.

Brain-computer interface (BCI) technology is being studied for use in Parkinson's Disease, cluster headaches, tinnitus, and motor rehabilitation after stroke.

IpsiHand™ is an FDA-approved device (FDA, April 2021) for use in individuals with a history of chronic stroke (six months or more post-stroke) who are 18 years or older, undergoing stroke rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremities. The device is designed to use EEG signals from the non-lesioned hemisphere to control the handpiece and complete the intended motion according to the type of signal detected. The IpsiHand™ system is contraindicated for individuals with severe spasticity or rigid contractures in the wrist and/or fingers, and for individuals with skull defects due to craniotomy or craniectomy.

Rustamov et al. (2024) conducted a prospective study evaluated the effectiveness of the IpsiHand™ in 26 chronic stroke individuals (mean post-stroke duration 69

months). Participants used the IpsiHand™ for 12 weeks (one hour a day, five days a week). The primary outcome, Upper Extremity Fugl-Meyer (UEFM) score, improved significantly across sessions ($p < 0.001$), with a mean increase of 8.1 points, exceeding the minimally clinically important difference (MCID = 5.25). These findings suggest that contralesionally-controlled BCI therapy induces clinically meaningful motor recovery in both proximal and distal upper extremity segments.

Humphries et al. (2022) conducted a non-randomized, prospective study to determine whether a contralesionally EEG-driven BCI reorganized brain networks for motor control. The study included eight individuals with upper limb hemiparesis at least six months post-stroke. Resting-state functional Magnetic Resonance Imaging (fMRI) scans and Median Upper Extremity Fugl-Meyer assessment (UEFM) data were recorded before and after the therapy period for 12 weeks. All BCI individuals showed an increase in UEFM score after 12 weeks of contralesional BCI therapy. Clinically meaningful recovery occurred in seven of the eight individuals. In addition, the authors noted that contralesional BCI therapy effectively enabled motor recovery for chronic hemiparesis. Moreover, motor functional connectivity strength and topographic extent decreased following BCI therapy.

Rustamov et al. (2022) conducted a small, prospective study to investigate whether motor recovery using a contralaterally controlled BCI in individuals with chronic stroke was associated with alterations in phase-amplitude coupling (PAC) between gamma and lower frequency. Seventeen individuals with chronic stroke with upper limb hemiparesis completed BCI therapy for 12 weeks. Following 12 weeks of BCI therapy, all participants found an increase in the UEFM score. In addition to the motor functional improvement, the study found increased theta-gamma coupling in bihemispheric motor regions. The authors concluded that the findings support the notion that specific cross-frequency coupling dynamics in the brain likely play a mechanistic role in mediating motor recovery in the chronic phase of stroke recovery.

HCPCS E0739: Motus Hand and Motus Foot rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors

A rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors describes a system comprised of a robotic exoskeleton and computer with an interactive interface to provide biofeedback on performance. The device is intended for use by individuals with a history of stroke and residual upper or lower extremity impairments to complete game-like training programs to challenge motor control. The Motus Hand and the Motus Foot are Class I devices

exempt from the pre-market notification and approval procedures by the Food and Drug Administration (FDA).

Mehrholtz et al. (2018) conducted a Cochrane review including 45 randomized controlled trials (n=1619) to assess the effectiveness of electromechanical and robot-assisted arm training for improving activities of daily living, arm function, safety, and arm muscle strength in individuals after stroke. The authors concluded that electromechanical and robot-assisted arm training after stroke may improve activities of daily living scores, arm function, and arm muscle strength. However, the authors noted that the results must be interpreted with caution although the quality of the evidence was high, because there were variations between the trials in the intensity, duration, and amount of training; type of treatment; participant characteristics; and measurements used.

Linder et al. (2015) conducted a randomized trial to examine the effects of an eight-week home-based robot-assisted rehabilitation coupled with a home exercise program compared with a home exercise program alone on depression and quality of life (QOL) in 99 individuals less than six months after stroke. The primary QOL outcomes were the Stroke Impact Scale (SIS) and the Center for Epidemiologic Studies Depression Scale (CES-D). The results of the study demonstrated that both interventions were effective in improving QOL and depression outcomes. The authors noted that for individuals after stroke with limited access to traditional therapy, home-based interventions may be a valuable intervention for continued non-motor recovery. The authors noted several limitations of the study including the inability to rule out spontaneous recovery or compensatory strategies after stroke given the participants inclusion criteria of stroke within the previous six months. Moreover, the authors noted that the data was retrieved via self-report and thus future studies should include more objective measurement of compliance, such as a wrist accelerometer or similar technology, to better understand the dose-effect relationship.

Wolf et al. (2015) conducted a randomized controlled trial to examine the efficacy of home-based telemonitored robotic-assisted therapy (Hand Mentor Pro) as part of a home exercise program (HEP) compared with a dose-matched HEP-only intervention among individuals less than six months post-stroke. The study included 99 hemiparetic participants with limited access to upper extremity rehabilitation. The participants were randomized to an experimental group which received combined HEP and HMP or a control group which received HEP only at an identical dosage. Both groups demonstrated improvement across all upper extremity outcomes including the Action Research Arm Test, Wolf Motor Function Test, and the Fugl Meyer Assessment (upper extremity). However, the authors noted multiple limitations to the study. The participants were less than six months post-stroke, and thus, spontaneous recovery may have contributed to functional motor improvement. The authors concluded that although the telerehabilitation component may be valuable in

individuals post-stroke with limited resources, future studies are needed to determine the efficacy of this intervention.

HPCPS E1700, 1701, 1702: Jaw Motion Rehabilitation System, replacement cushions for jaw motion rehabilitation system, replacement measuring scales for jaw motion rehabilitation system

Jaw stretch devices include, but are not limited to, the TheraBite® Jaw Motion Rehabilitation System™ and the OraStretch™ Press Jaw Motion Rehab System™. U.S. Food and Drug Administration (FDA) Mechanical stretching devices are classified by the FDA as Class I medical devices.

A jaw stretch device is placed between the teeth and turned to gradually open the jaw to improve mandibular range of motion after trismus and mandibular hypermobility. Trismus is a condition characterized by limited ability to open the jaw, which is generally caused by a combination of spasm, fibrosis, and contraction of the muscles responsible for movement at the temporomandibular joint. Distances of 20 to 40 mm have been suggested as indicative of trismus. Trismus is a common complication of oral cavity and oropharyngeal cancers and is usually due to a combination of factors, including direct tumor invasion, surgery, and/or radiation therapy.

A randomized controlled trial by Salloum et al. (2024) compared four interventions for masticatory myofascial pain (MPS): ultrasound therapy, stabilization splint (SS), TheraBite® device, and masticatory muscle exercises in 80 individuals over 4 weeks, with follow-up at two and five months. Pain intensity (VAS) and mandibular mobility were primary outcomes. By week four, pain decreased from severe to mild in the ultrasound, stabilization splint, and TheraBite® groups, while the exercise group improved to moderate pain. TheraBite® was less effective than ultrasound and the splint for rapid pain relief ($p = 0.012$ and $p = 0.013$, respectively) but significantly better than exercises at week two ($p = 0.046$). At five-month follow-up, all groups showed mild pain with no significant differences. TheraBite® improved mandibular mobility, particularly right and left lateral movements, and was significantly better than exercises for lateral movement at week 2 (LLM $p = 0.001$; RLM $p = 0.003$). However, after five months, all groups achieved similar mobility improvements.

A retrospective cohort case studied completed by Kamstra et al. (2013) evaluated the effects of TheraBite® exercises to treat trismus in individuals with head and neck cancer ($n=69$). The results of this study demonstrated an average increase in mouth opening of 5.4mm. However, authors cited limitations such as compliance assessment, lack of a control group, and a non-blinded assessment of mouth opening that may have led to an over- or underestimation of the effect of TheraBite® exercises. The authors noted that further research is needed including a randomized controlled trial study design.

In a retrospective, pilot cohort study, Stubblefield et al. (2010) examined the effectiveness of the DTS as part of a multi-modal treatment strategy for trismus in

individuals with head and neck cancer (n=20). The investigators reported an overall improvement of the maximal interincisal distance (MID) from 16.5 mm to 23.5 mm ($p < 0.001$) with the use of the DTS with the concurrent use of physical therapy, pain medication, and botulinum toxin injections. The investigators concluded that the DTS is a safe and effective component of a multi-modal strategy for improving trismus associated with head and neck cancer and its treatment. However, the investigators noted that further research is needed including large, randomized prospective trials to determine the relative effectiveness of the treatment modalities available for trismus including physical therapy and other jaw stretching devices.

Pauli et al., (2015) conducted a comparative study to examine the effectiveness of two different jaw exercise devices. Fifty individuals with head and neck cancers were randomized to jaw exercise with either the TheraBite® or Engström jaw device in a 10-week exercise program. The results of the study demonstrated that both groups improved their mouth opening, 7.2 mm (22.9%) and 5.5 mm (17.6%) for TheraBite® and Engström, respectively. Moreover, the largest increase in mouth opening and highest compliance to exercise was seen during the four first weeks. The authors concluded that jaw exercise therapy effectively improved mouth opening capacity and led to less trismus-related symptoms. However, the authors noted that follow-up time was limited, and compliance to exercise was self-reported through a diary. The authors recommended a qualitative approach to better investigate compliance as well a study with more study individuals to potentially detect larger differences between the jaw devices.

HPCPS E3200: Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only

Walking rehabilitation options are often lacking during the chronic phase of stroke recovery, even though many individuals with chronic stroke impairment report ongoing difficulties with walking. Slow walking is associated with a higher fall risk and reduced quality of life. The InTandem™ neurorehabilitation system applies the principles of rhythmic auditory stimulation, which allows the device to autonomously provide a progressive intervention through adjustments to the tempo and beat salience.

Awad et al. (2024) conducted a prospective, randomized controlled trial (n=87) to evaluate the safety and efficacy of the InTandem™ device to improve post-stroke walking. Participants were placed in 5-week walking interventions with or without InTandem™. InTandem™ improved the 10-meter walking speed twice as much compared to active controls with three times more responders and similar safety.³³

González-Hoelling et al. (2024) conducted a systematic review of 21 studies (n=948) examining rhythmic auditory stimulation (RAS) for gait rehabilitation after stroke, focusing on real-world walking ability. The authors concluded that RAS, delivered through metronomes or music, improved gait speed, cadence, stride length, and

balance compared with baseline or conventional therapy, indicating a clear benefit for basic walking parameters. The authors concluded that while RAS is a promising tool for enhancing gait and balance after stroke, more rigorous and standardized trials are needed to clarify its impact on functional ambulation.

Smayda et al. (2023) evaluated the efficacy of the InTandem™ system to ensure it could be safely and effectively used by stroke survivors (n=15) in a home environment without professional supervision. The vast majority (93%) successfully performed all critical tasks without errors that could compromise safety or effectiveness, and no adverse events were observed.

HCPCS E0469, A7021: Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device, Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)

High-frequency assisted airway clearance (HFAC) systems utilize rapid pressure or oscillatory pulses—either into the airway, out of the lungs, or both—to mobilize mucus from the airways, helping it move toward larger airways where it can be coughed or suctioned. HFAC systems integrate positive expiratory pressure (PEP) and oscillatory positive airway pressure (PAP) therapies with built-in nebulizers to enhance aerosol delivery, promote lung expansion and secretion clearance, and shorten overall treatment duration. The nebulizer type, circuit design, and handset integrity are critical factors for effective lung delivery during high-frequency assisted airway clearance therapy.

In a 2024 in vitro study, BiWaze® delivered significantly more aerosol to the lungs than Volara™ (28% vs. 6.2%; $P \leq .001$). Compared to the Volara™, BiWaze® showed greater oscillatory positive airway pressure and great greater inhaled lung doses of radioaerosol. Volara™ also had much higher nebulizer losses (58% vs 7.2%). The authors recommended not generalizing results, considering the different delivery options that could be applied in home settings. The authors also recommended more research to evaluate the clinical efficiency of these therapies on secretion clearance and the restoration of lung function.³⁶

HCPCS E1399: Apos® customized biomechanical footwear device

Reichenbach et al. (2020) conducted a randomized controlled trial (n=220) to evaluate the effectiveness of biomechanical footwear (AposTherapy) compared to control footwear for the treatment knee osteoarthritis (OA). At 24 weeks, outcome measures improved, including pain, physical function, and stiffness. The authors noted multiple limitations to the study. First, there were differences in the appearance of the biomechanical footwear and the control footwear. Moreover, the authors reported a lack of blinding, longer daily wear of the footwear device in the experimental group, and allowance of supplemental analgesic use. Lastly, the authors cited limited

generalizability of the study, as the trial was conducted at a single center and the individuals included in the study may not be an accurate representation of individuals with knee pain due to OA. The authors concluded that further research is needed to assess long-term efficacy and safety before determining the clinical effectiveness of this device.

Greene et al. (2023) conducted a retrospective study to evaluate the efficacy of a biomechanical device (Apos® system) in individuals with knee OA who met the criteria for orthopedic referral for Total Knee Replacement (TKR). The primary outcome measure was the incidence rate of TKR within two years since beginning treatment with the Apos® device. Secondary outcome measures examined clinical effect, including a reduction in pain and an improvement in function using standard Patient Reported Outcome Measures and computerized gait analysis. The investigators reported that at six months after starting treatment with the Apos® device, pain decreased by 42%, function improved by 39%, and the Oxford Knee Score (OKS) increased by 7.6 points. Moreover, two years after follow-up, 305 of 365 (84%) of individuals who used the Apos® system who met criteria for TKR did not progress to having surgery.

Drew, et al. (2022) performed a retrospective study to examine the effectiveness of the use of a biomechanical device (Apos® system) in individuals with end-stage knee OA who were eligible for TKR. The primary outcome measure of the study was the avoidance of TKR surgery rates at the end of a two-year follow-up for individuals selecting the biomechanical intervention and for control individuals selecting surgery from the time of their enrollment into the study. Secondary outcomes included the measurement in the changes in clinical symptoms at one year after initiation of the intervention. The authors reported that 204 of 237 individuals (86%) who utilized the Apos® system avoided TKR at two years. In addition, the clinical outcomes of the Apos® system at one year demonstrated a significant improvement, including an estimated 36% reduction in pain, a 34% reduction in disability, and a 13% increase in physical aspects of quality of life, as well as a significant improvement in gait patterns after the intervention. The authors noted multiple limitations to the study, including the need for longer term data collection, the possibility of selection bias in the control group, and an inability to collect follow-up clinical metrics because of poor patient adherence to follow-up appointments.

HPCPS L6700: An intent decoding module or pattern recognition add-on module for an upper limb myoelectric prosthetic device (e.g., Coapt Complete Control Gen2; Ottobock Myo Plus)

Transradial amputation is the most common major upper limb amputation, and it affects individuals' functioning capabilities due to the loss of the hand. Myoelectric hand prostheses provide individuals with the ability to perform multiple grips. Simon et al. (2023) conducted a study (n=8) to investigate how individuals with transradial amputations performed using a multi-articulating prosthetic hand with pattern recognition and direct control. Results showed that while control strategies enabled prosthetic use

in daily life, pattern recognition control offered advantages in task performance and user satisfaction for some individuals. The Assessment of Capacity for Myoelectric Control (ACMC) outcome measure showed a significant improvement of 21%.⁴⁰

Woodward and Hargrove (2019) tested a novel algorithm that adjusted control parameters dynamically based on user performance. Individuals (n=8) trained with a virtual prosthetic arm, and the system adapted to their muscle signals to optimize control. The study demonstrated that real-time adaptation led to improved accuracy and reduced training time, suggesting that integrating adaptive algorithms into prosthetic control systems could enhance usability and reduce the burden of manual recalibration. In this study, there were several limitations: However, it did not assess long-term usability, durability of control improvements, or user satisfaction over extended periods. Also, while the algorithm showed benefits, the study did not include a direct comparison to conventional myoelectric control systems in real-world prosthetic devices, limiting its clinical relevance.

Ghosh et al. (2024) conducted a systematic review of 80 studies to get a better understanding of how brain signals relate to upper limb movement, in the context of assistive technologies. The authors highlighted that non-stationary EMG signals, along with issues like electrode displacement and limb-position variability, significantly degrade system performance — often causing a 14–21% drop in classification accuracy in practical scenarios.

A 2024 review by Wang et al. explored how myoelectric interfaces could be made easier to use by reducing the calibration burden. The study looked at robust pattern recognition methods that could decrease device set up time as well as rely on less calibration data. To address the limitations of purely data-driven approaches, emerging research is integrating physiological modeling into pattern recognition frameworks. By incorporating musculoskeletal dynamics and biomechanical parameters (e.g., muscle force estimation, joint kinematics), these hybrid models can better account for inter- and intra-user variability in EMG signals.

HCPCS L8701, L8702: myoelectric and/or power enhanced upper extremity orthotic device (e.g., MyoPro® 2)

Upper extremity impairment occurs in an estimated 80% of individuals after a stroke, and meaningful recovery typically occurs in the first six months after stroke. Approximately 5% of individuals affected with upper extremity impairment regain full arm function post stroke. However, recovery is important post stroke; upper extremity impairments can influence quality of life as it can impact activities of daily living (ADL). There are studies that have shown that home-based therapies can improve quality of life, improve satisfaction, and reduce caregiver strain.

Chang et al. (2024) conducted a retrospective study (n=19) of individuals aged 65+ with chronic stroke who used the MyoPro® at home. Pre- and post-treatment DASH

(Disabilities of the Arm, Shoulder & Hand) scores showed a mean improvement of 18.07 points ($P < 0.0001$) representing a statistically and clinically significant gain in functional independence. Limitations to this study include small sample size, the lack of prescribing a frequency or engagement in therapy or home exercise programs, which may have affected individuals' reports of functional change and the lack of categorizing individuals by kind of stroke or severity of deficits.⁴⁴

Page et al. (2020) conducted a single-blinded randomized controlled trial (RCT) ($n=34$) to compare three 8-week interventions: Myomo combined with repetitive task-specific practice (RTP); RTP alone; or Myomo therapy only. All groups showed equivalent improvement (comparable motor recovery); however, the Myomo group demonstrated greater gains in patient-reported outcomes.

Magnetic shoe inserts (i.e. orthosis with magnetic foil)

Magnetic shoe inserts are recommended for a variety of health concerns, including chronic plantar fasciitis, a pain in the inner area of the heel bone. These insoles typically offer a massaging effect while the individual is walking, as well as offering comfort through the thicker insoles.

Winemiller et al. (2003) conducted a double-blind RCT to determine whether magnetic insoles offer superior pain relief compared to identical non-magnetic (sham) inserts. The study randomly assigned 101 adults with heel pain (≥ 30 days) to wear cushioned insoles embedded with active bipolar magnets or sham magnets for 8 weeks. Both groups experienced significant reductions in morning foot pain; there were no differences in pain core or impact on work enjoyment ($P > .70$). The authors concluded that magnetic insoles did not provide additional benefit over non-magnetic insoles in reducing plantar heel pain.

Kirthika et al. (2023) performed a randomized controlled trial (RCT) to compare the clinical efficacy of standard cushioned insoles compared to magnetic insoles in adults with chronic plantar fasciitis. Forty participants (aged 30-45) were randomized into two groups: cushioned insole or magnetic insole. Both groups showed significant improvement post-intervention; however, the group with the magnetic insoles demonstrated greater pain reduction ($P \leq 0.001$) than the group with the cushioned insole. The authors opined that insoles, combined with stretching, provided significantly greater pain relief and functional improvement compared to cushioned insoles alone in chronic plantar fasciitis. Further large-scale studies are warranted.⁴⁷

HPCPS L3649: Foot adductus positioning device (e.g., UNFO foot brace) for the treatment of metatarsus adductus

A foot adductus positioning device (e.g., Universal Neonatal Foot Orthotic (UNFO) foot brace) is a pre-molded corrective device intended for the treatment of metatarsus

adductus, a congenital inward curvature of the forefoot in newborns, also referred to as "in-toeing." According to the FDA approval for this device, the UNFO brace is a Class I device, classified as a corrective orthotic shoe. The UNFO brace is a below the ankle orthosis that provides continuous pressure.

Treatment of metatarsus adductus often involves initial observation, as spontaneous resolution is present in a majority of cases. Management of the condition depends on degree of flexibility, and in some cases where no improvement is seen by six months of age, passive stretching or serial casting may be recommended. Moderate to severe deformities may persist if the condition is untreated and can potentially lead to osteoarthritis, ankle instability, or tendon issues. The UNFO brace addresses moderate to severe deformities through non-invasive correction between ages 4 months to 11.5 months. Foot deformities should be corrected prior to the individual's ability to bear weight on the feet.⁴⁸

A 2022 (Freedman et al.) retrospective cohort study compared the UNFO brace with serial casting for infants with metatarsus adductus. Outcomes in 147 feet (n=94) showed similar correction success, comparable recurrence and complication rates, but a shorter full-time treatment phase with UNFO. Families found UNFO easier to use and less disruptive. The authors concluded that UNFO is an effective, convenient alternative to casting, though evidence is limited by the study's non-randomized, single-center design.²⁵

Panski et al. (2021) conducted a prospective study to evaluate the effectiveness of UNFO in treating moderate-to-severe metatarsus adductus in infants aged 4 months to 11.5 months. A total of 114 affected feet (n=73) were treated using the UNFO brace worn for 23 hours per day, followed by a gradual weaning phase. Results showed that 98 feet demonstrated significant improvement, while 11 showed no change and three worsened. The authors concluded that UNFO is a safe and effective alternative to casting for correcting metatarsus adductus in young infants.

HCPCS L2006: Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated

HCPCS L2006 describes a custom fabricated, single or double upright knee ankle foot orthosis (KAFO) with an adjustable microprocessor control feature which provides resistance to stance and swing phase knee joint motion. The custom fabricated KAFO can be constructed from thermosetting materials, thermoplastics, or composite type materials. There are no additional add-on codes for this KAFO.

A custom fabricated, single or double upright KAFO with an adjustable microprocessor control (stance control orthosis) is purported to assist individuals with significant knee instability, neuromuscular impairments, or paralysis. Unlike traditional locked KAFOs,

which hold the knee rigid throughout gait, this type of orthosis uses embedded sensors and a microprocessor to dynamically control both stance (weight-bearing) and swing (leg advancement) phases of walking. The device reports to detect gait patterns in real time and adjust resistance or support accordingly, allowing for a more natural, reciprocal gait, improved safety on uneven terrain or stairs, and reduced energy expenditure. Examples of stance control devices include the E-MAG Active, the Sensor Walk, and the C-Brace® (Ottobock, Vienna, AT).

Stance control devices have not been clearly established as superior to conventional devices and there is limited evidence to suggest it is considered equivalent. Moreover, given the significant cost of microprocessor variants, mechanical models are recommended over microprocessor-controlled devices at this time. (Ontario Health [Quality], 2021).

Bruggenjurgen et al. (2024) conducted a cross-sectional survey across six German orthotic clinics to evaluate patient-reported outcomes using a microprocessor-stance-and-swing-control knee-ankle-foot orthosis (MP-SSCO, e.g., C-Brace) compared to prior use of traditional KAFOs. Twenty-one individuals responded, 14 of whom previously used standard KAFOs. Results indicated that 78.6% had experienced falls with traditional KAFOs which significantly decreased to 42.7% with MP-SSCO use ($p < 0.01$); stair descent ability improved markedly ($p < 0.01$), and 71.4% reported enhanced participation in activities. Pain ratings decreased from 3.8 to 2.8 on a 1–5 scale, although this change did not reach statistical significance ($p = 0.06$).

Ruetz et al. (2024) performed a randomized-controlled study ($n = 102$) to evaluate the impact of a microprocessor-controlled stance and swing orthosis (C-Brace) on individuals reliant on KAFOs. The number of individuals with Berg Balance Scale (BBS) scores below 40 (indicating high fall risk) dropped from 36 to 16. Fall rates decreased markedly from an average of 4.0 to 1.1. Additionally, the C-Brace significantly improved balance, reduced fall risk, and enhanced mobility, functional performance, and quality of life compared to conventional KAFOs.

HCPCS L5991: Osseo-integrated external prosthetic connector device

HCPCS code L5991 describes a complete endoskeletal product that is used as an osseo-integrated external limb prosthetic connection device. The product provides a standard connection between an osseo-integrated implantable limb component and endoskeletal prosthetic components.

The OPRA™ Implant System—including Axor II—was approved by the FDA in 2020 for transfemoral amputees with trauma or cancer who have difficulty using conventional socket prostheses. Per the contraindications, this device is not for individuals with: incomplete skeletal growth, osteoporosis, high weight (>220 lbs), vascular disease, diabetes with complications, poor stump skin, active infection, or inability to follow-up.

The Axor II serves as the detachable external connector between the abutment and the prosthesis.

The U.S. Department of Veterans Affairs A Clinical Determination (June 2024) classified the OPRA™ Implant System incorporating the Axor#II connector as may be considered medically necessary for transfemoral amputees with socket-related problems (e.g., skin infection, scarring, perspiration, stump volume fluctuation).

Hagberg et al. (2020) provided evidence supporting the use of bone-anchored transcutaneous prostheses, specifically the OPRA™ system which includes the Axor II connector. Over a 15-year follow-up of 111 transfemoral amputees, the study found sustained improvements in prosthetic use, mobility, and overall quality of life. Implant survival was high (89% at 7 years and 72% at 15 years), though mechanical complications were common, particularly among more active users.

Hoellwarth et al. (2020) provided a review of osseointegration for amputees, detailing current implant types, surgical techniques, and rehabilitation protocols. The authors reported that osseointegrated prostheses typically offer greater mobility, higher patient satisfaction, and increased wear time compared to traditional socket systems.

Rehani et al. (2024) conducted a systematic review of 38 studies evaluating bone-anchored prostheses (BAP) for transfemoral amputees, including clinical outcomes, complications, patient-reported experiences, and cost-effectiveness. The review found consistent improvements in health-related quality of life, mobility, and prosthesis wear time following osseointegration, particularly among individuals who struggled with socket-based systems. While superficial soft-tissue infections were the most common complication, serious adverse events such as deep infections or implant failures were rare.

Copes spinal scoliosis brace

The Copes Spinal Scoliosis Brace, also known as the Copes Scoliosis Brace or COPES Scoliosis Treatment Recovery System (STRS), is a dynamic, air-injected spinal orthosis designed to correct spinal curvature in scoliosis. The brace uses pneumatic force vector pads to apply adjustable corrective pressure to spinal curves, purported to reduce curvature and rotation in scoliosis individuals.

Zarzycka et al. (2009) conducted a review article describing "alternative methods" of treatment of idiopathic scoliosis that mentions the Copes system but does not present clinical outcome data or cite supporting trials. The majority of documented outcomes are anecdotal or internally reported by the Copes clinics.

HCPCS L5969, L5973: Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type of motors(s), Endoskeletal ankle foot

system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Power-assisting endoskeletal ankle-foot addition (HCPCS L5969) is an add-on motorized assistance module designed for use with endoskeletal ankle-foot prostheses. The device provides active power assistance during plantarflexion and dorsiflexion, reducing user effort and enhancing gait dynamics. The device supports mobility in users requiring additional propulsion or lift, especially beneficial on inclines or during propulsion phases of walking. The device is often used in high-activity transtibial amputees to improve gait symmetry and comfort.

Microprocessor-controlled endoskeletal ankle-foot system (HCPCS L5973) is a fully integrated ankle-foot prosthesis with embedded on-board sensors and microprocessor controls. The device continuously monitors gait dynamics (e.g., angle, velocity) and actively adjusts resistance or provides active power to support dorsiflexion/ plantarflexion. The device is purported to enhance walking stability, reduces trip risks, and adapts to different terrain and cadence automatically.

A 2022 cross-sectional study by Cacciola et al. evaluated Empower, a commercially available microprocessor foot with powered propulsion, users and found significant reductions in sound-side knee pain, amputated-side knee pain, and low-back pain, along with improved functional outcomes measured by KOOS-ADL and the Oswestry Disability Index. Earlier biomechanical trials, including those by Herr and Grabowski (2012), Ferris et al. (2012), and Esposito et al. (2016), demonstrated that Empower improves gait normalization, stair ascent mechanics, and energy efficiency compared to passive feet.

HCPCS E0683: Non-pneumatic, non-sequential, peristaltic wave compression pump

A non-pneumatic, non-sequential, peristaltic wave compression pump (i.e., Venowave VW5 [Therma Bright, Inc., Massillon, OH]) is a series, battery-operated device containing a series of peristaltic pumps that generate a wave-form motion. The device is intended for individuals 18 years of age or older and purports to improve vascular and lymphatic flow in the lower limbs. The FDA-cleared indications for use include management of the symptoms of post-thrombotic syndrome (PTS), prevention of deep vein thrombosis (DVT), prevention of primary thrombosis, and treatment of lymphedema.

O'Donnell et al. (2008) performed a randomized, crossover controlled trial to evaluate Venowave for the treatment of severe PTS. The participants wore Venowave and a sham/control device (eight weeks each). Clinical improvement occurred in 10 (31%) participants receiving Venowave and four (13%) participants receiving the control device, with too (6%) participants reporting a clinical success with both devices ($p = 0.11$). Mean VEINES-QOL score at the end of study period was significantly greater (p

= 0.004) for Venowave compared to control. Mean Villalta scale (a clinical tool used to assess the severity of PTS) score at the end of study period was significantly decreased ($p = 0.004$) for Venowave compared to control.

Sobieraj-Teague et al. (2012) performed a randomized controlled trial comparing Venowave and standard care versus standard care alone in high-risk neurosurgical individuals (often anti-coagulation constrained) ($n=150$). Venous thromboembolism (VTE) occurred in three individuals randomized to Venowave and in 14 individuals randomized to control (4.0% vs 18.7%, $p = 0.008$). Similar reductions were observed for proximal DVT (2.7% vs 8.0%) and symptomatic VTE (0% vs 2.7%), and the results were consistent in all subgroups examined.

Makedonov et al. (2020) conducted a review article and noted that venous-return assist devices such as the Venowave can be tried for individuals with moderate-to-severe PTS symptoms that are unresponsive to elastic compression stocking. However, the author emphasized that data are very limited and such devices are not supported by robust clinical trials in the PTS population.

HPCPS E0767: Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories

HPCPS E0767 is a device that delivers amplitude-modulated RF electromagnetic fields intrabuccally, intended for systemic cancer therapy via oral administration.

Intrabuccal administration purports to enable the safe, systemic delivery of very low levels of electromagnetic fields (EMF), as evidenced by therapeutic responses in organs such as the femur, liver, adrenal glands, and lungs. In vitro research has shown that tumor-specific frequencies, identified in individuals with various cancer types, can inhibit tumor cell growth in a manner that is both tissue- and tumor-specific. Intrabuccal administration of 27.12 MHz radiofrequency has shown to result in long-term objective responses in individuals with cancer and has not demonstrated any significant adverse effects.

A 2019 study by Jimenez et al. found that exposing liver cancer cells to 27.12MHz significantly slowed tumor growth ($p < 0.01$). In mice, tumors shrank and cancer stem cells were reduced, and early patient data showed similar benefits without adverse effects on human tissue. The results suggest this could provide a safe, non-invasive therapy for liver cancer.

However, there is a lack of well-designed, peer-reviewed clinical trials evaluating the safety and long-term effectiveness of amplitude-modulated radiofrequency electromagnetic field therapy, including its impact on outcomes such as mortality.

HCPCS A8005, A8006: Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted, Powered, cable driven assist glove, hand, finger, includes pressure sensors, glove replacement only

HCPCS A8005 is a microprocessor device that detects user intent and provides powered assistance to finger movement, improving functional hand use during activities of daily living for individuals with neurologic or neuromuscular impairments. HCPCS A8006 describes a replacement glove component with integrated sensors only, without motors, control units, or power supply. This code is used when replacement of the glove component is required due to wear or changes in hand fit, while the powered system remains functional.

In a 2024 systematic review, Jiryaei and Jafarpisheh evaluated the usefulness of assistive soft robotic gloves, including cable-driven designs, for rehabilitation of individuals with hand impairment by synthesizing findings from 15 peer-reviewed studies involving a total of 210 participants. The included studies assessed outcomes such as performance on functional tasks, grip strength, range of motion, and user satisfaction, with most studies reporting short-term improvements in select functional or strength-related measures. However, only one randomized controlled trial was identified among the included studies, while the remaining evidence consisted primarily of small observational studies with heterogeneous designs, variable intervention protocols, and inconsistent outcome measures. Sample sizes across individual studies were limited, and follow-up durations were generally short, restricting evaluation of durability of benefit and long-term functional impact. Quantitative outcomes were inconsistently reported, and clinically meaningful endpoints related to sustained independence in activities of daily living were often absent or insufficiently measured. The authors also noted substantial variability in device actuation methods, study populations, and assessment tools, which limited comparability across studies and precluded robust conclusions regarding effectiveness. Based on these limitations, the review concluded that although some soft robotic gloves appeared promising, the overall quality of evidence remained low and insufficient to support routine clinical use.

HCPCS A4479: Electronic transanal irrigation system, includes electronic pump, water reservoir, tubing, and accessories, without catheter, any type

HCPCS A4479 is a system designed to assist with regulated rectal irrigation in individuals with neurogenic bowel dysfunction or chronic bowel evacuation difficulties. The electronic pump delivers controlled volumes of water at a regulated pressure to promote predictable bowel evacuation, helping reduce constipation, fecal incontinence, and associated complications. These systems are typically used by individuals with spinal cord injury, spina bifida, multiple sclerosis, or other neurologic conditions to support effective bowel management.

In a 2020 prospective, open-label, non-comparative, multicenter pilot study, Charvier et al. evaluated the feasibility and short-term use of a transanal irrigation system incorporating an electronic pump in 15 individuals who were already familiar with transanal irrigation techniques. The intervention was assessed over a one-month period during which five consecutive irrigations were performed, with the primary outcome defined as procedural success based on achievement of usual irrigation volume, stool evacuation, and absence of leakage between irrigations. Fourteen individuals were included in the primary analysis, and the reported success rate was 72.4% , corresponding to 21 successful procedures out of 29 evaluated irrigations. Despite this procedural success rate, bowel dysfunction scores measured at the end of the study did not differ significantly from baseline, indicating no measurable improvement in bowel function outcomes. No serious adverse events or device-related adverse events were reported; however, only 50% of individuals expressed willingness to continue use of the device after study completion. The study was limited by a very small sample size, short follow-up duration, absence of a comparator group, reliance on individuals with prior transanal irrigation experience, and use of surrogate procedural outcomes rather than clinically meaningful health outcomes. These limitations substantially restricted the generalizability of the findings and precluded conclusions regarding long-term effectiveness, comparative benefit over existing non-powered irrigation systems, or net health benefit.

In this 2025 systematic review and management guidance, Vollebregt et al. evaluated the existing evidence regarding transanal irrigation for individuals with chronic constipation and/or fecal incontinence. The review included studies of heterogeneous design, including randomized trials, observational studies, and case series, with substantial variability in study populations, irrigation protocols, outcome measures, and follow-up duration. Although some studies reported improvements in bowel-related symptoms and quality-of-life measures, the authors noted that the overall quality of evidence was low, with many studies characterized by small sample sizes, limited statistical power, high attrition rates, and short-term follow-up. Quantitative outcome measures were inconsistently reported, and clinically meaningful endpoints were often lacking or inadequately defined, limiting the ability to assess net health benefit. The authors also identified wide variability in discontinuation rates across studies, ranging from 0% to over 40%, as well as frequent minor adverse events, further complicating interpretation of effectiveness. The review emphasized persistent evidence gaps related to long-term safety, durability of benefit, optimal patient selection, and comparative effectiveness among different transanal irrigation systems, including mechanically assisted or electronic devices. Based on these limitations, the authors concluded that while transanal irrigation may have a role in selected individuals, the existing evidence base remained insufficient to support broad, standardized adoption of specific device types, underscoring the investigational nature of related technologies.

In a 2022 comprehensive systematic review, Kabir et al. evaluated power-assisted and robotic hand rehabilitation devices, including sensor-enabled and cable-driven glove systems. The authors analyzed 35 devices described across peer-reviewed literature, with a focus on design characteristics, actuation mechanisms, control systems, and reported clinical outcomes. The reviewed studies primarily involved individuals with hand impairment due to stroke or neurologic conditions and were largely exploratory in nature, with most studies utilizing small sample sizes, observational designs, and short-term intervention periods. Quantitative outcomes were inconsistently reported and frequently limited to surrogate measures such as grip strength, range of motion, task completion, or device usability, with limited assessment of sustained functional improvement or independence in activities of daily living. The review identified a lack of standardized outcome measures, absence of uniform device design standards, and minimal use of randomized controlled trial methodology, which significantly limited comparisons across studies and weakened the overall evidence base. Few devices were supported by clinical trials, and those that were evaluated demonstrated heterogeneous results with insufficient statistical power to establish clinical effectiveness. The authors concluded that existing hand rehabilitation devices, including powered assist glove systems, lacked adequate clinical validation and that current evidence was insufficient to support routine clinical implementation.

HPCPS L2221: Addition to lower extremity orthosis, ankle system, microprocessor-controlled feature plantarflexion and/or dorsiflexion, includes power source

HPCPS L2221 is a system that includes an integrated microprocessor and power source that continuously adapts ankle movement in response to user motion and loading conditions. This addition is intended to enhance stability, alignment, and functional ankle motion during ambulation. Microprocessor-controlled ankle systems may help improve gait efficiency, reduce compensatory movements, and increase safety during walking.

In a 2024 multicenter, randomized, controlled crossover trial, Ruetz et al. evaluated a microprocessor-controlled stance and swing control knee–ankle–foot orthosis in 102 individuals who were dependent on knee–ankle–foot orthoses for ambulation due to lower extremity paresis. Participants were randomized to use either the microprocessor-controlled orthosis or their conventional knee–ankle–foot orthosis for three months, followed by crossover to the alternate device for an additional three months. The primary outcome was balance as measured by the Berg Balance Scale, which improved by a mean of 3.3 points with the microprocessor-controlled system compared with the conventional orthosis, a difference that reached statistical significance. Secondary outcomes included self-reported falls, mobility, function, and quality-of-life measures, with reported reductions in mean falls from 4.0 to 1.1 and statistically significant improvements across several functional and patient-reported domains. Despite these

findings, the study evaluated an integrated knee–ankle system and did not isolate the independent clinical contribution of microprocessor-controlled ankle plantarflexion or dorsiflexion features alone. The study population was highly selected, limited to ambulatory individuals able to safely trial advanced orthotic technology, which constrained generalizability. Follow-up duration was limited to three-month treatment periods, precluding assessment of long-term durability, safety, and sustained functional benefit. In addition, the crossover design and reliance on functional and self-reported outcomes introduced potential bias.

In a 2024 cross-sectional, retrospective survey study, Brüggjenjürgen et al. evaluated perceived burden, outcomes, and quality-of-life measures among 21 individuals with neuromuscular knee instability who had used a microprocessor-controlled stance and swing control knee–ankle–foot orthosis for a mean duration of approximately two years, with 14 individuals also reporting prior experience using a conventional knee–ankle–foot orthosis. Outcomes were assessed using a self-developed, internet-based questionnaire that relied on participant recall of experiences with previous orthotic devices, with comparisons made between current and prior orthosis use. The study reported improvements in self-rated mobility, activities of daily living, pain, and frequency of falls with use of the microprocessor-controlled system; however, quantitative outcome data were limited, and fall frequency demonstrated substantial variability, with a reported combined annual fall frequency of 67.9 events prior to microprocessor-controlled orthosis use. The study design was limited by a very small sample size, reliance on retrospective self-report and recall, absence of objective functional outcome measures, and lack of prospective or randomized comparison. Additionally, the study did not isolate the independent contribution of microprocessor-controlled ankle plantarflexion or dorsiflexion features, as the evaluated device functioned as an integrated knee–ankle system. Manufacturer involvement among authors further introduced potential conflict of interest and bias.

HPCPS E2403: External ocular negative pressure pump, electric

HPCPS E2403 is a device designed to apply programmable negative pressure around the eyes with the intent of lowering intraocular pressure during use. It is meant to be used in individuals with glaucoma. The device typically consists of sealed goggles connected to an electronic pump that creates localized negative pressure around the eyes.

In a 2019 prospective, open-label, randomized pilot study by Samuelson et al., 20 eyes from 10 individuals with open-angle glaucoma, glaucoma suspect status, or ocular hypertension were evaluated to assess the safety and tolerability of the Multi-Pressure Dial (MPD) during 8 hours of continuous negative pressure application. No statistically significant changes were observed in intraocular pressure (IOP), best-corrected visual acuity (BCVA), tear break-up time (TBUT), retinal nerve fiber layer thickness, or slit lamp and fundus examination findings immediately after treatment or at the 1-week follow-

up (all $p > .05$). Mean IOP in study eyes changed from 15.8 ± 4.4 mmHg at baseline to 14.6 ± 4.0 mmHg immediately after treatment and 15.5 ± 3.2 mmHg at 1 week. Only one adverse event, a headache, was reported and resolved by the end of the study visit. The authors concluded that sustained application of negative pressure through the MPD for 8 continuous hours appeared safe and well tolerated. However, interpretation of these findings was limited by the very small sample size, single-site design, short follow-up period, open-label methodology, and evaluation of safety outcomes only, which restricted the ability to draw conclusions regarding long-term safety, effectiveness, or generalizability.

In a 2020 prospective, open-label, randomized study by Ferguson et al., 20 eyes from 10 individuals with mild open-angle glaucoma were evaluated to assess the safety and tolerability of the MPD when worn overnight for seven consecutive days. Before the 7-day wear period, mean IOP decreased from 18.2 ± 3.8 mmHg to 14.0 ± 2.1 mmHg, representing a 23% reduction ($p < .01$). After seven nights of wear, mean IOP decreased from 16.9 ± 4.1 mmHg to 13.5 ± 3.7 mmHg with active negative pressure, corresponding to a 20% reduction and an absolute decrease of 3.4 mmHg ($p < .01$). No statistically significant changes were observed in baseline IOP measurements, best-corrected visual acuity, retinal nerve fiber layer measurements, or ophthalmic examination findings following the study period, and no intraocular pressure spikes of 10 mmHg or greater were reported. Subject-reported tolerability and comfort ratings were generally favorable throughout the study, and no serious safety concerns were identified. The authors concluded that overnight use of the MPD for seven consecutive nights appeared safe, well tolerated, and capable of producing clinically meaningful nocturnal IOP reduction in addition to existing glaucoma therapies. However, the findings were limited by the small sample size of only 10 individuals, the single-site and open-label design, inclusion of only individuals with mild open-angle glaucoma, the lack of long-term follow-up, and the absence of efficacy outcomes related to disease progression. As a result, the generalizability of the results and the long-term clinical effectiveness of the device remained uncertain.

In the HERCULES trial, 93 individuals with normal-tension glaucoma were randomized in a fellow-eye controlled design, and 120 eyes ($n=60$) completed the 52-week study without protocol deviations. In the per-protocol population, 88.3% (53/60) of study eyes achieved a daytime intraocular pressure (IOP) reduction of at least 20% compared with 1.7% (1/60) of control eyes (95% CI [73.7%, 94.1%], $P < .001$). For the nocturnal endpoint, 96.7% (58/60) of study eyes achieved an IOP reduction of at least 20% compared with 5.0% (3/60) of control eyes (95% CI [79.7%, 97.8%], $p < .001$). No device-related serious adverse events occurred. The most common adverse events were lid edema (11.8% of study eyes vs. 1.1% of control eyes) and periorbital edema (12.9% vs. 1.1%). The authors concluded that the ocular pressure adjusting pump safely and effectively lowered both daytime and nocturnal IOP in individuals with normal-tension glaucoma and addressed an unmet need for nonpharmacologic nocturnal

IOP reduction. However, evidence directly demonstrating improvement in clinically meaningful outcomes such as visual field preservation, reduced glaucoma progression, reduced need for additional intervention, functional outcomes, or quality of life was not established. Also, there was significant attrition with only 60 individuals completing the study. Study limitations included the absence of patient-reported outcomes, limited subgroup analyses due to sample size, and the contralateral intrasubject study design, which the authors noted was not representative of typical real-world bilateral device use (Ferguson et al, 2025).

Codes Addressed in This Guideline

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Note:

There may be additional items considered Experimental, Investigational, or Unproven. This list is not intended to be inclusive of all items.

HCPCS	Description
A4479	Electronic transanal irrigation system, includes electronic pump, water reservoir, tubing, and accessories, without catheter, any type
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
A4543	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month
A4593	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller
A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each

HCPCS	Description
A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
A6614	Supplies and accessories for use with an external ocular negative pressure pump, any type, per month
A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)
A8005	Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted
A8006	Powered, cable driven assist glove, hand, finger, includes pressure sensors, glove replacement only
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device
E0683	Non-pneumatic, non-sequential, peristaltic wave compression pump
E0721	Transcutaneous electrical nerve stimulator for nerves in the auricular region
E0732	Cranial electrotherapy stimulation (CES) system, any type
E0736	Transcutaneous tibial nerve stimulator
E0737	Transcutaneous tibial nerve stimulator, controlled by phone application
E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories
E0739	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
E0743	External lower extremity nerve stimulator for restless legs syndrome, each
E0765	Fda approved nerve stimulator, for treatment of nausea and vomiting
E0767	Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories

HCPCS	Description
E1399	Apos® customized biomechanical footwear device
E1700	Jaw motion rehabilitation system
E1701	Replacement cushions for jaw motion rehabilitation system, pkg. of 6
E1702	Replacement measuring scales for jaw motion rehabilitation system, pkg. of 200
E2403	External ocular negative pressure pump, electric
E3200	Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5973	Endoskeletal ankle-foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source
L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L3649	Orthopedic shoe, modification, addition or transfer, not otherwise specified
L2006	Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
L2221	Addition to lower extremity orthosis, ankle system, microprocessor-controlled feature plantarflexion and/or dorsiflexion, includes power source

HCPCS	Description
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any motor type
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector

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