MEDICAL POLICY

Excellus
An independent licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY DETAILS	
Medical Policy Title	**Transcutaneous and Percutaneous Nerve Stimulation as a Treatment for Pain and Other Conditions**
Policy Number	**1.01.01**
Category	**Contract Clarification**
Original Effective Date	**03/06/02**
Committee Approval Date	**03/27/03, 04/22/04, 04/28/05, 06/22/06, 06/28/07, 06/26/08, 06/25/09, 06/24/10, 06/24/11, 10/25/12, 06/27/13, 10/24/13, 08/28/14, 06/25/15, 06/22/16, 06/22/17, 06/28/18, 06/27/19, 06/25/20, 06/24/21, 03/24/22, 03/23/23, 03/21/24**
Current Effective Date	**07/15/24**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, transcutaneous electrical nerve stimulators (TENS), including the BioniCare Stimulator Model BIO-1000, and H-wave Stimulation have been medically proven to be effective and, therefore, are considered **medically appropriate** for pain when **ALL** of the following criteria have been met:
   A. symptoms persist for greater than three months;
   B. failure of physical therapy, osteopathic manipulative therapy, or chiropractic therapy;
   C. failure of medications (e.g., simple analgesics, nonsteroidal anti-inflammatory drugs (NSAIDS), or opioids); **and**
   D. a 30-day trial period has demonstrated efficacy of the treatment.

II. Based upon our criteria and assessment of the peer-reviewed literature, U.S. Food and Drug Administration (FDA)-approved, form-fitting conductive garments utilized for the delivery of TENS, will be considered **medically necessary** when the criteria in policy statement I is met, the nerve supply to the stimulated area is intact and at least **ONE** of the following criteria apply:
   A. Treatment includes a large stimulation area or considerable number of stimulation sites and the member cannot reasonably manage the treatment without the use of the garment;
   B. The stimulation site is not accessible with standard electrodes, adhesive tape or lead wires; **or**
   C. A skin or other medical condition exists that would prevent the adherence of standard electrodes, tapes or lead wires.

III. Based upon our criteria and assessment of the peer-reviewed literature, TENS and H-wave stimulation do not improve patient outcomes and, therefore, are considered **not medically necessary** for the following indications:
- A. the relief of pain in labor and vaginal delivery;
- B. treatment of headaches and/or migraines;
- C. visceral abdominal pain;
- D. temporomandibular joint (TMJ) disorder;
- E. cancer pain;
- F. essential tremor;
- G. low back pain; **or**
- H. neck pain.

IV. Based upon our criteria and assessment of the peer-reviewed literature, electrical stimulators (e.g., BioniCare Stimulator Model BIO-1000, SofPulse, OrthoCor Active Knee System, MedRelief ST Series) have not been medically proven to be effective to facilitate the repair of cartilage in patients with arthritis and, therefore, are considered **investigational** for this indication.

V. Based upon our criteria and assessment of the peer-reviewed literature, the following stimulation devices have not been proven medically effective and, therefore, are considered **investigational** for all indications:
- A. Peripheral Nerve Stimulation (PNS):
  1. Permanent PNS systems (e.g., Moventis PNS, StimQ, Nalu);
  2. Temporary PNS system (e.g., SPRINT)
- B. Percutaneous Electrical stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT)
- C. Restorative Neurostimulation Therapy (e.g., ReActiv8)
- D. Interferential Stimulation (e.g., RS 4i Sequential Stimulator, Empi IF 3Wave)
- E. External Trigeminal Nerve Stimulation (eTNS) (e.g., Monarch)
- F. Transcutaneous Supraorbital Neurostimulation (e.g., Cefaly)
- G. Remote Electrical Neuromodulation (REN) devices (e.g., Nerivio)
- H. Afferent Patterned Stimulation Therapy for Essential Tremor (e.g., Cala One, Cala Trio)
- I. Cranial Electrical Stimulation (e.g., Alpha Stim-AID, Carvella, CES Ultra)
- J. Peripheral Magnetic Stimulation (e.g., Axon Therapy, MagVenture Pain Therapy)
- K. Single Pulse Transcranial Magnetic Stimulation (e.g., SpringTMS) for the treatment of headache/migraine
- L. Transcutaneous/nonimplantable Vagus Nerve Stimulation (tVNS)
- M. Devices capable of delivering multiple modalities such as interferential stimulation, electrical stimulation and neuromuscular electrical stimulation (e.g., TruWave Plus, NexWave, Empi Continuum).

VI. Repair and/or replacement of a medically necessary stimulator, accessories, and/or components not under warranty will be considered **medically appropriate** when the following criteria are met:
- A. Physician documentation includes **ALL** of the following:
  1. date of device initiation;
  2. manufacturer warranty information;
  3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **AND ONE OF THE FOLLOWING APPLY:**
     - a. Repair of the currently used device when **ALL** of the following are met:
       - i. it is no longer functioning adequately,
       - ii. Inadequate function interferes with activities of daily living, **and**
       - iii. repair is expected to make the equipment fully functional (as defined by manufacturer);

       OR
     - b. Replacement of the currently used device when the following are met:
       - i. it is no longer functioning adequately, **AND** any of the following:
         - a. has been determined to be non-repairable, **or**
         - b. the cost of the repair is in excess of the replacement cost;

OR

c. Replacement of the currently used device when **BOTH** of the following are met:
   i. there is documentation that a change in the patient's condition makes the present unit non- functional, **and**
   ii. improvement is expected with a replacement unit.

VII. Repair or replacement of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VIII. The replacement of properly functioning stimulator and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

Refer to Corporate Medical Policy #1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

Refer to Corporate Medical Policy #1.01.48 Functional Electrical Stimulation (FES) and Neuromuscular Electrical Stimulation (NMES)

Refer to Corporate Medical Policy #7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

Refer to Corporate Medical Policy #3.01.09 Transcranial Magnetic Stimulation

Refer to Corporate Medical Policy #8.01.20 Acupuncture and Auricular Electrostimulation

Refer to Corporate Medical Policy #7.01.10 Sacral Nerve Stimulation

Refer to Corporate Medical Policy #8.01.22 Tibial Nerve Stimulation (TNS) for Voiding Dysfunction

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Coverage of durable medical equipment is contract dependent unless required under Federal or State mandates.

II. The use of TENS therapy is a relative contraindication in patients with a pacemaker or an implantable cardioverter defibrillator (ICD). Electrical interference from the TENS unit has been reported and may interfere with the proper functioning of these devices.

DESCRIPTION

This policy addresses certain types of electrical stimulation devices. The U.S. Food and Drug Administration (FDA) has approved many stimulation devices based on their substantial equivalence to predicate devices. There are devices for both home and clinic use. Altering the frequency, intensity, location and pulse duration of the devices allows them to be marketed individually.

I. Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is the application of an electrical current through the skin to stimulate the nervous system. The first device was patented by Medtronic Inc and has since been utilized to relieve pain in a portable, noninvasive way. The device delivers mild pulsed electrical currents through electrode pads placed on the surface of the skin. Users can change the frequency, intensity, and pulse duration of the TENS based upon the patient's comfort and response. The intensity of the TENS device can be altered to a comfortable sensation without motor contraction, to the highest level of motor contractions (noxious). Traditional TENS is delivered utilizing high-frequency, low intensities and small pulse durations. Noxious level TENS have been investigated for patients with chronic pain.

II. TENS for the Treatment of Arthritis

The BioniCare Bio-1000 stimulator (VQ OrthoCare) was cleared for marketing by the FDA in 1997 through the 510(k) process to deliver pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee and was then later approved for rheumatoid arthritis of the hand. The FDA originally determined that this device was substantially equivalent to TENS devices. In 2006, the FDA reclassified the device as a transcutaneous electrical stimulator for arthritis upon the manufacturer's request given that the target tissue is not nerve, but rather joint tissue. The BioniCare System consists of an electronic stimulator device with electrical leads placed over the affected area and is held in place with a lightweight, flexible wrap, and self-adhesive fasteners.

The OrthoCor Active Knee System (OrthoCor Medical; acquired by Caerus Corp) uses pulsed electromagnetic field energy at a radiofrequency of 27.12 MHz to treat pain. In 2009, the OrthoCor Knee System was cleared for marketing by the FDA through the 510(k) process and is classified as a short-wave diathermy device for use other than applying therapeutic deep heat. It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue and for the treatment of muscle and joint aches and pain associated with overexertion, strains, sprains, and arthritis.

In 2008, the SofPulse (also called Torino II, 912-M10, and Roma; Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing by the FDA through the 510(k) process as a short-wave diathermy device that applies electromagnetic energy at a radiofrequency of 27.12 MHz. The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

III. H-wave Stimulation

H-wave stimulation is a form of electrical stimulation that differs from others given its waveform. It emits a prolonged pulse width/duration and can produce effective anesthesia/analgesia without weakness or tetany with extended use such as that which is seen with neuromuscular electrical stimulation. H -wave devices are available for home use as durable medical equipment. H-wave stimulation has been used for pain control, treatment of diabetic neuropathy, muscle sprains, TMJ dysfunctions or reflex sympathetic dystrophy. It has also been used to accelerate healing of wounds (e.g., diabetic ulcers).

IV. Peripheral Nerve Stimulation (PNS)

PNS is a similar concept to TENS but different in that electrodes are implanted around or adjacent to the nerve serving the painful stimuli and then stimulated using a pulse generator and remote control. A trial of treatment is typically required prior to permanent implant of the generator and/or electrodes. Success of the trial is defined as >50% reduction in pain response. PNS is generally reserved for patients who fail to get pain relief from TENS, medications, physical therapy and/or injection therapy.

The Moventis PNS (Micron Medical Corporation) received FDA approval in May 2020 based upon substantial equivalence to The Freedom Spinal Cord Stimulator (SCS) System (Curonix) and an implanted peripheral nerve stimulator (StimQ PNS, Stimwave Technologies) for pain management. All of the devices are intended to treat adults who have severe intractable chronic pain of peripheral origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach and are not intended to treat pain in the craniofacial region of the body.

The Nalu Neurostimulation (Nalu Medical, Inc.) system was cleared by the FDA as both a SCS (K183047), and PNS (K183759, K191435) in June 2020. The treatment involves the initial use of adhesive clips and non-functioning Therapy Discs to determine future stimulation location and comfort level, followed by a temporary trial of the implanted leads, prior to permanent implantation.

The SPRINT Peripheral Nerve Stimulation System (SPR Therapeutics, Inc.) received FDA clearance in 2017. Considered a temporary device, SPRINT uses a percutaneous electrode placed via an introducer needle near target peripheral motor or sensory nerves. The insertion of the implant does not require incisions or anesthesia and the indwelling leads are left in place for up to 60 days. The device utilizes 300-micron diameter leads (one quarter the size of conventional neurostimulation leads) to provide a safe lead withdrawal at the completion of the treatment.

The device is intended to provide symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain. It is not intended to treat pain in the craniofacial region of the body.

V. Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT)

PENS and PNT are terms often used interchangeably in the literature. This form of stimulation utilizes very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue. PENS and PNT are also not to be confused with acupuncture using electrical stimulation. In electrical acupuncture, needle electrodes are inserted below the skin, but not necessarily at the site of pain. They are placed according to acupuncture meridians, which are a concept of Chinese medicine. *Please refer to Corporate Medical Policy #8.01.20 Acupuncture and Auricular Electrostimulation for information regarding acupuncture.*

VI. Restorative Neurostimulation Therapy

In 2020, the ReActiv8 (Mainstay Medical) device was FDA approved through the Premarket Approval (PMA) process (PMA P190021) and is a permanent implant indicated for adults with intractable chronic low back pain associated with multifidus dysfunction who have failed pain medications and physical therapy and are not candidates for spine surgery. The device components consist of an implantable pulse generator, stimulation leads, software and programmer wand, activator and magnet. ReActiv8 is marketed as the first and only restorative neurostimulation therapy to treat mechanical chronic low back pain and is full body MRI conditional.

VII. Interferential Stimulation (IFS)

IFS is an anti-inflammatory based treatment modality. The interferential stimulator crosses two medium frequency alternating currents, which penetrate deep into soft tissue. It is intended for use in the treatment of circulation disorders, range of motion issues, edema and muscle spasms. It is reported to stimulate bone healing, inhibit pain and promote soft tissue healing. A number of interferential stimulator devices have received FDA approval including the Medstar 100 (Mednet Services and the RS-4V (RS Medical).

VIII. External Trigeminal Nerve Stimulation (eTNS)

The Monarch eTNS system, (NeuroSigma) was approved by the FDA on April 19, 2019 through the De Novo process and classified as a transcutaneous electrical nerve stimulator for attention deficit hyperactive disorder device type. It is designed to generate and deliver electrical pulses to the trigeminal nerve, which directs signals to the parts of the brain that are believed to be associated with ADHD. The device is connected to a small patch that adheres to a patient's forehead. It is meant for at-home use during sleep and requires caregiver supervision.

IX. Transcutaneous Supraorbital Neurostimulation

The Cefaly device (CEFALY Technology) received FDA approval on March 11, 2014 for the prophylactic treatment of migraines in patients ages 18 years and older. Cefaly is a small, portable, battery-powered, prescription device that resembles a plastic headband worn across the forehead and atop the ears. The user positions the device in the center of the forehead, just above the eyes, using a self-adhesive electrode. The device applies an electric current to the skin and underlying body tissues to stimulate branches of the trigeminal nerve, which has been associated with migraine headaches. The user may feel a tingling or massaging sensation where the electrode is applied. The device should only be worn daily for 20 minutes.

X. Remote Electrical Neuromodulation (REN)

The Nerivio device (Theranica) was approved by the FDA in May of 2019, and in January of 2021, it was approved for adolescent use. It is a wireless stimulation device applied to the lateral upper arm in 45-minute sessions and triggers weak electrical impulses to start conditioned pain modulation, a proprietary electrical signal to stimulate noxious sensory fibers and relieve acute migraine. It is controlled by a mobile app that includes a migraine diary to track migraine headaches and treatment sessions. Each device functions for 12 treatments after which, it is to-be disposed of and a new device is required.

XI. Afferent Patterned Stimulation Therapy for Essential Tremor

An external upper limb tremor stimulator, the Cala Trio (Cala Health) received FDA approval October 5, 2021. It is a hand-specific device indicated to relieve tremors in adults with essential tremor. The device is worn like a wristwatch. Electrodes embedded into a disposable cloth band deliver stimulation to the median and radial nerves of the wrist after being calibrated to the specific motion of the user. The digital display provides prompts, time, offers the ability to adjust intensity and notifies the user when the band requires changing. The contained accelerometer measures the tremor and adjusts simulation. Sessions are for 40-minutes and the device is recommended to be used twice daily prior to activities requiring use of that hand.

XII. Cranial Electrical Stimulation (CES)

CES is also known as cranial electrotherapy, transcranial electrical stimulation or electrical stimulation therapy. One CES**,** the Alpha Stim-AID*, Alpha-Stim*~~)~~ is a handheld prescription device that delivers an electronic microcurrent through electrodes placed further from the brain (i.e., earlobes, scalp, eyelids) and delivers a pulsed, low-intensity current to stimulate specific groups of nerve cells. Although the exact mechanism of action is unknown, CES has been approved by the FDA for the treatment of insomnia, depression, and anxiety. The user can select the level of stimulation and increase or reduce as needed, typically for 20- minute sessions. CES is being evaluated for a variety of other conditions including pain, and functional constipation.

XIII. Peripheral Magnetic Stimulation

Axon Therapy (NeuraLace Medical, Inc.) was the first FDA approved peripheral magnetic stimulation device. The device received FDA approval through the Section 501(k) premarket approval process in May 2021. Axon therapy utilizes a figure-8 shaped coil to deliver focused magnetic pulses to damaged A-Beta sensory nerve fibers during a 13-minute treatment and is intended to simulate peripheral nerves for the relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years and older. MagVenture Pain Therapy devices (Tonika Elektronik A/S) were approved in August of 2023 and intended for use in the hospital and clinics.

XIV. Single-Pulse Transcranial Magnetic Stimulation (sTMS)

The SpringTMS (eNeura Therapeutics, LLC) received FDA approval through the 510 (k) notification process. It is a handheld device positioned on the occipital bone on the back of the head. The user presses a button to deliver a single magnetic pulse of 0.9T, generating an electrical current that causes electromagnetic induction of neurons over the target area. The device is indicated for the treatment of acute pain associated with migraine headache with aura.

XV. Transcutaneous/Nonimplantable Vagus Nerve Stimulation (tVNS)

tVNS is a medical treatment that involves delivering electrical impulses to the auricular or cervical branch of the vagus nerve. It has been proposed as an adjunctive treatment for certain types of treatment-resistant depression, tinnitus, diabetes, endotoxemia, memory, myocardial infarction, headache, pain, intractable epilepsy, and stroke.

In May 2017, the gammaCore-S (electroCore LLC), a noninvasive vagus nerve stimulation device, was cleared for marketing through the Section 510(k) process for the acute treatment of adults with episodic cluster headaches. When the device is applied to the side of the neck by the patient, a mild electrical stimulation of the vagus nerve is carried to the central nervous system. Each stimulation using gammaCore-S lasts two minutes. The patient controls the stimulation strength. In 2021, the gamma-Core Sapphire received FDA approval for the pre-market notification intent as a substantiated equivalent to the predicate device, with additional indications for use including the preventative treatment of migraine headache in adolescent (age 12 and older) and adult patients, the acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients, and for the adjunctive use for the preventative treatment of cluster headache in adults.

XVI. Multimodal Electrotherapy Stimulation Devices

Combination transcutaneous electrical nerve stimulation, interferential stimulation and neuromuscular electrical stimulation devices are TENS devices capable of delivering any of the three modalities depending on electrode

arrangement on the body and programming options. This type of device is intended to treat a wide variety of symptoms especially for acute and chronic pain relief. The TruWave Plus, NexWave, and Empi Continuum are examples of ~~a~~ combination devices.

RATIONALE

Transcutaneous Electrical Nerve Stimulation and H-Wave Stimulation

TENS and H-Wave Muscle Stimulators have a treatment effect beyond that of a credible placebo. Their use may be justified in those individuals with mild acute or chronic pain who wish to use a nonpharmacological form of analgesia. An abstract of 101 patients presented at the 2004 annual meeting of the American Academy of Orthopedic Surgeons reported that 50% of patients avoided total knee arthroplasty by using the BioniCare system. However, there was no randomly assigned control group in this abstract. The FDA classified this device as a TENS unit, however, the manufacturer has indicated that it is a new category of device, as it uses a different array of proprietary electrical amplitudes than a TENS unit and does not function to stimulate nerves. Instead, the BioniCare device is purported to stimulate chondrogenesis. However, no studies have been performed to evaluate whether chondrogenesis occurs with use of this device.

Centers for Medicare & Medicaid Services (CMS) has posted a Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain. Chronic low back pain is defined as an episode of low back pain that has persisted for three months or longer that is not a manifestation of a clearly defined and generally recognizable primary disease entity (e.g., cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus). The Decision Memo states that TENS is not reasonable and necessary for the treatment of chronic low back pain. In order to support additional research on the use of TENS for chronic low back pain, CMS will cover TENS when the member is enrolled in an approved clinical study meeting all of the requirements listed in the Decision Memo. Case reports have indicated that a TENS has been known to interfere with pacemakers and implantable cardioverter defibrillators (ICDs).

Peripheral Nerve Stimulation

The American Society of Pain and Neuroscience developed clinical guidelines for the use of implantable peripheral nerve stimulation in the treatment of chronic pain (2022). Through a systematic review process, 20 randomized controlled trials and 33 prospective observational studies were reviewed. The authors identify that the literature pertaining to PNS neuromodulation is in its early stages. The goal of the assessment conducted was to fill gaps of current knowledge with the consensus opinions of an expert panel. The authors report that literature supports the efficacy of PNS for the treatment of chronic migraine headaches, chronic hemiplegic shoulder pain, failed back surgery syndrome, and lower extremity neuropathic and post-amputation pain, graded at a IB level of evidence. The authors identified that further robust clinical studies identifying specific conditions, waveforms, programming and lead placements are necessary to ensure standardization of patient and treatment selection.

The North American Spine Society released clinical guidelines for multidisciplinary spine care in the diagnosis and treatment of low back pain in 2020. In response to a question on the effectiveness of electrical stimulation for decreasing the duration of pain, decreasing intensity of pain, increasing functional outcomes and improving return to work status, when compared to natural history plus or minus medication, the authors state “A systematic review of the literature yielded no studies to adequately address this question.”

Percutaneous Electrical Stimulators (PENS) and Percutaneous Neuromodulation Therapy (PNT)

PENS and PNT have been investigated for the treatment of headache, diabetic neuropathy, chronic neck pain, chronic low back pain, chronic surface hyperalgesia, and musculoskeletal pain. A systematic review conducted by Plaza-Manzano and colleagues (2020) concluded that PENS could decrease the level of pain intensity, but not related disability, in musculoskeletal pain disorders. The overall level of evidence, however, was low and there was heterogeneity in the application methods.

Beltran-Alacreu et al. (2022) evaluated the effectiveness of PENS compared to TENS on the reduction of musculoskeletal pain. This systematic review and meta-analysis included a total of nine RCTs in the qualitative analysis, with seven in the quantitative analysis. Overall, there was low-quality evidence for increased pain intensity reduction with PENS over TENS, but the difference found was not deemed to be clinically significant. When only studies with low risk of bias were meta-analyzed, there was a moderate quality of evidence that there is no difference between TENS and PENS for pain intensity. Six out of the nine studies presented high risk for the blinding of participants, and seven out of nine were high risk for blinding of personnel. Beyond these two items, the risk of bias in the included trials was either low or unclear. Protocols and parameters for the application of PENS and TENS were heterogenous across all trials, leading to the conclusion that there is still high uncertainty regarding the effectiveness of PENS for musculoskeletal pain.

Gilmore and colleagues (2021) performed a prospective multi-center study aimed at characterizing the responses of percutaneous medial branch peripheral nerve stimulation (PNS) to see if results from earlier, smaller single-center studies and reports were generalizable when performed on a larger number of patients refractory to nonsurgical treatments. Participants (n=89) with chronic lower axial backpain, a pain score greater than or equal to four, had failed at least two different categories of treatments and had at least four weeks of stable analgesic medication usage were enrolled, eight of which were later to be found ineligible because they did not meet the predefined criteria at the baseline. The target sample size to obtain a 95% confidence interval for the primary endpoint was 90. Authors report enrollment stopped short due to COVID-19. Exclusions included history of lumbar surgery, however, 10 of the patients with a history of lumbar surgery were included as part of a prospectively designed substudy with revised exclusion criteria. Participants were implanted with percutaneous PNS leads from the SPRINT PNS System under ultrasound and/or fluoroscopic guidance and were left in place for up to 60-days, when leads were removed. Follow up was planned for 12 months after the two-month PNS treatment. The study was not completed, and follow-up beyond 8 months is on-going. Clinically and statistically significant reductions in pain intensity, disability, and pain interference were reported by a majority of participants. 73% of participants were successes for the primary end point, reporting clinically significant (≥30%) reductions in back pain intensity after the 2-month percutaneous PNS treatment (n = 54/74). Whereas prospective follow-up is ongoing, among those who had already completed the long-term follow-up visits (n = 51), reductions in pain intensity, disability, and pain interference were sustained in a majority of participants through 14 months after the start of treatment. Limitations of the study include lack of randomization and control group.

There are no well-designed randomized controlled studies in the medical literature comparing PNS to established treatment options or a sham procedure; and studies on larger populations with longer follow-up are needed to permit scientific conclusions regarding the benefit and improved health outcomes for the use of PNS.

Restorative Neurostimulation Therapy

The FDA approval of the ReActiv8 system was based on a 2020 randomized control trial by Gilligan and colleagues (ReActiv8-B, NCT02577354). The authors have since published two-year and three-year durability studies on the same participants (Gilligan et al 2021, 2023). The pivotal trial was a multicenter sham-controlled RCT enrolling 204 individuals with chronic, refractory low back pain. All participants were permanently implanted with the system. Therapeutic group participants (n=102) received active treatment of the medial branch of the dorsal ramus nerve for 30-minutes twice daily. The control group (n=102) received low level sham stimulation. The primary endpoint was the difference in proportions of responders in the treatment and control groups. Response was defined as having a 30% or greater reduction in visual analog scale (VAS) and no increase in pain medications, assessed at 120 days. Following the 120-day randomized phase, participants in the control group were given the option to cross over to the intervention group and were followed along with the participants from the intervention group for up to three years. At 120 days, there was no difference between groups on the primary endpoint of treatment response (57.1% intervention vs 46.6% sham; p =.1377) or the individual components of the primary endpoint. The study investigators conducted prespecified secondary analyses of the primary outcome data, including the between-group difference in VAS at 120 days, a review of participants with increased pain medications, and a cumulative-proportion-of-responders analysis, which graphically displays the proportion of responders across the range of all possible cutoffs and is described as having greater statistical power than the comparison of proportions of the dichotomized primary outcome. The VAS mean change from baseline to 120 days favored the

intervention group (-3.3 vs -2.4; p =.032), but it is unclear if the difference between groups (0.9 points) was clinically meaningful. The cumulative proportion-of-responders analysis similarly favored the intervention group (p =.0499). Nine participants in both the intervention and control groups had an increase in pain medication at 120 days, but the increase was unrelated to low back pain in 6 of 9 participants in the treatment group versus 0 of 9 in the control group. Most importantly, the controlled phase was only 120 days. In the longer-term, uncontrolled follow-up phase of the trial, there was continued improvement in VAS scores over time in those who were assessed. Data was available for 176 of 204 participants at 1 year (86.3%), 156 of 204 participants (79%) at two years, and 130 of 204 (63.7%) at three years. The limitations of the studies, including a lack of a control group and high attrition limits drawing conclusions from these results. Additional evidence from longer-term sham-controlled RCTs is needed.

Inferential Stimulation

Hussien et al. (2021) included 19 trials in a meta-analysis of patients (N=1167) to analyze the efficacy of IFS in alleviating musculoskeletal pain. Two trials compared IFS with placebo and the pooled mean difference in pain was significantly reduced with IFS versus a placebo (-0.98; 95% confidence interval [CI], -1.42 to -0.54; p<.0001), but this was not demonstrated in the six (6) trials comparing IFS to other interventions (-0.04; 95% CI, -0.20 to 0.12; p<.65). When used as an adjunct to other pain interventions, IFS did not significantly improve pain compared with placebo in four (4) studies (-0.06; 95% CI, -0.6 to0.48; p=.82) or compared with active treatment in eight (8) studies (0.02; 95% CI, -0.88 to 0.92; p=not reported). The authors concluded that IFS reduced musculoskeletal pain when used as a single agent compared with placebo, but this is limited by the small number of trials (n=2) and patients enrolled.

External Trigeminal Nerve Stimulation (eTNS)

McCough et al. (2019) assessed the efficacy and safety of TENS in a double-blind, sham-controlled pilot study of pediatric patients with Attention Deficit Hyperactivity Disorder (ADHD). The study was a four -week trial followed by one blinded week without intervention. Clinical assessments included weekly clinician-administered ADHD-Rating and Clinical Global Impression (CGI) scales, and quantitative electroencephalography (EEG) at baseline as well as at week four. The primary outcome measure was the clinician completed ADHD-Rating Scale total score. Results revealed that ADHD-Rating Scale totals showed significant group-by-time interactions, demonstrating a differential treatment effect (F=8.12; df=1/228; p=.005). The CGI-Improvement scale also favored active treatment over sham (p=.003). Quantitative EEG readings were obtained in both groups but there were no participant specific correlations to other outcomes. No serious adverse events were observed in either group and no patient withdrew from the study due to adverse events. Significant increases in weight and pulse were seen with active TENS over the trial period; however, no differences between active and sham TENS with regard to blood pressure were seen. Conclusions were that TENS therapy is efficacious and well-tolerated in pediatric patients with ADHD. Limitations cited were the small sample size and relatively short duration of treatment and follow-up.

Transcutaneous Supraorbital Neurostimulation

The peer-reviewed literature concerning the use of transcutaneous supraorbital neurostimulators for the treatment of migraine headaches consists of results from the Prevention of Migraine (PREMICE) trial of 67 patients randomized to receive the Cefaly device or sham treatment daily for 20 minutes for three months. After the first month of treatment both the treatment and sham groups showed a decrease in migraine days by an average of 20%. This decrease disappeared in the sham group by the second and third month but continued in the treatment group. The 50% responder rate was greater in the treatment group, and the therapeutic gain of effective stimulation over sham was 26%. The monthly attack frequency from the first to the third month was reduced by 18.8% in the treatment group and by only 3.5% in the sham group. Headache severity and the monthly intake of anti-migraine medications was also reduced in the treatment group. No adverse events or side effects were found for either the treatment or sham group. Compliance was moderately satisfactory in both groups. The responder rate for electrical stimulation was within the range of those reported for other migraine treatment modalities. However, the study size was small, and the individuals in the selected cohort were not severely disabled by their migraines.

Remote Electrical Neuromodulation

The FDA market authorization for Nerivio was based on a vendor- funded double blind RCT from Yarnitsky, et al. (2019) involving 252 patients at 12 different sites who met the international classification of headache disorders criteria for migraine, had two to eight migraines per month and less than 12 headache days per year. The authors aimed to evaluate the efficacy and safety of REN for the acute treatment of migraine. Treatment sessions with the device were 45 minutes. Pain relief was defined as improvement from severe or moderate pain to mild or none, or improvement from mild pain to none, of which 66.7% of the active treatment group achieved pain relief at 2 hours post-treatment compared to 38% in sham group. Sustained relief (48 hours post treatment) was achieved by 39% of the treatment group, and in 16% of the sham group. Adverse events were mild and rare. The authors report that the findings are equivalent to migraine relief found with triptan use. The approval of Nerivio for adolescents was based on a study by Hershey and colleagues (2020), a vendor-funded single-arm multicenter study of 39 patients with migraine between the ages of from the ages of 12 and 17. Pain relief at 2 hours was achieved by 71% (28/39) of the patients, and 35% (14/39) were pain free within 2 hours. Study enrollment was shortened to 60% of the planned target due to the coronavirus pandemic however since pain relief at 2 hours was achieved by more than 60% it was determined to be complete. Of those that had pain relief and pain freedom, 90% had sustained relief or freedom for 24 hours. Additional symptoms of nausea, photophobia and phonophobia disappeared at 2 hours in 54%, 41% and 40% of treated individuals. There were mild and low device related adverse events for both of the studies. The writers concluded that Nerivio is both safe and effective for the treatment of acute migraine in adolescents. Longer and larger RCTs with relevant comparators are needed to determine if results can be replicated in other populations, and if the treatment is superior to the current standard of care.

Afferent Pattern Stimulation

Pahwah et al. (2018) studied the use of a novel peripheral (radial and median nerves) stimulation device for the treatment of essential tremor via a RCT of 77 patients and compared to sham stimulation. Although the primary endpoint (an improvement in the Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) Archimedes spiral scores) was not met, the authors noted significant improvements in some subject-rated tasks in activities of daily living and clinical global impression-improvement (CGI-I) rating after stimulation. The outcomes were similar to the ranges of improvement offered by standard medications utilized for the treatment of tremor. The authors concluded that peripheral nerve stimulation may provide a safe, well-tolerated, and effective treatment for transient relief of hand tremor symptoms, however future studies over time and multiple sessions are needed.

Isaacson et al. (2020) evaluated the repeated home use of an FDA-cleared wrist-worn neuromodulation device in the Prospective Study for Symptomatic Relief of Essential Tremor with Cala Therapy (PROSPECT) trial. For each active treatment session, the device electrically stimulated the median and radial nerves for 40 minutes with an alternating burst pattern tuned to the frequency of each patient's tremor. The pre-specified co-primary endpoints were improvements on the clinician-rated Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) and patient-rated Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores. Of the 263 enrolled patients, 205 completed the visit three follow-up and were included in the primary analysis. Results revealed a significant improvement in TETRAS and BF-ADL from pre- to post-stimulation at each clinic visit ($p<.0001$ for all comparisons). Pre-stimulation tremor levels were improved from Visit 1 to 3 on both TETRAS and BF-ADL ($p<.0001$ for both). Patients rated as "severe" or moderate" improved with both TETRAS (49.3% at baseline to 21% at study exit) and BF-ADL (64.8% at baseline to 23% at study exit) scoring. Tremor power is a calculation of amplitude and frequency. Tremor power decreases with lower amplitude motions and lower frequency motions. Tremor power was also noted to significantly improve with therapy from pre- to post-stimulation ($p<.0001$). No device-related serious adverse events were reported. Non-serious device-related adverse events occurred in 18% of patients (e.g., persistent skin irritation, sore/lesion, discomfort, electrical burns, and minor skin irritation). Conclusions were that the repeated in home use of this neuromodulation device over three months was effective and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses.

Cranial Electrical Stimulation (CES)

CES has been investigated for individuals with headache, chronic pain, depression, and Parkinson disease. Trials that studied headache found only marginal benefits. Trials studied for chronic pain did not show a benefit. The evidence for the use of CES for psychiatric, behavioral, or neurologic conditions include a systematic review and a number of small sham-controlled RCTs, only one of which (Barclay et al, 2014) found a significant benefit for its use in depression, but the sample size was small with strong potential placebo effects. Additionally, studies had significant heterogeneity in study populations and treatment protocols.

Ahn et al. (2020) published a double-blind, randomized, sham-controlled pilot study of the feasibility and efficacy of remotely supervised CES via secure videoconferencing in 30 older adults with chronic pain due to knee osteoarthritis. Mean age was 59.43 years. CES was delivered via the Alpha-Stim M Stimulator, which was preset at 0.1 mA at a frequency of 0.5 Hz, and applied for one hour daily on weekdays for two weeks. The sham electrodes were identical in appearance and placement, but the stimulator did not deliver electrical current. The study was conducted in a single center in Houston. All 30 participants completed the study and were included in the outcome analyses. For the primary outcome of clinical pain at two weeks as assessed by a Numeric Rating Scale, a significantly greater reduction occurred in the active CES group (-17.00 vs. +5.73; $p<.01$). No patients reported any adverse effects. Important relevancy limitations include lack of assessment of important health outcomes or long-term efficacy. An important conduct and design limitation is that it is unclear how convincing the sham procedure was as it did not involve any feature designed to simulate a tingling sensation and give the patient the feeling of being treated (i.e., subtherapeutic amplitude, initial current slowly turned to zero). Therefore, findings may be subject to the placebo effect. This trial was also limited by the small number of participants. These limitations preclude drawing conclusions based on these findings.

Wu et al. (2020) published a double-blind, randomized, sham-controlled trial of the efficacy and safety of CES as an add-on treatment for tic disorders in 62 children and adolescents who lacked a clinical response to prior treatment of four weeks of pharmacotherapy. Cranial electrotherapy stimulation was delivered via the CES Ultra stimulator (American Neuro Fitness LLC) at 500 μA-mA and applied for 30 minutes daily on weekdays for 40 days. The sham CES was delivered at lower than 100 μA. The study was conducted at a single academic medical center in China. A total of nine participants (14.5%) discontinued the intervention early and were excluded from the analyses. There was no significant difference between the active CES and sham groups in the change in Yale Global Tic Severity Scale (YGTSS) score (-31.66% vs. 23.96%; $p=.13$).

Kim et al. (2021) reported on a three-week randomized, double-blind, sham-controlled trial evaluating the effectiveness of home-based CES (n=25) versus sham treatment (n=29) in nonclinical patients with daily anxiety. Novel, headphone-like, in-ear electrodes were used in this study. Results demonstrated a significant reduction in anxiety scores using the State Anxiety Inventory (SAI) with CES versus sham stimulation treatment. Depression inventory scores did not significantly differ between groups. Limitations of this study included the use of a small sample of nonclinical patients, short follow-up, post-randomization withdrawals that did not contribute data to the analysis, and the unclear clinical significance of a decreased anxiety inventory score.

Single-Pulse Transcranial Magnetic Stimulation (sTMS)

Transcranial magnetic stimulation has established treatment protocols and is considered a safe modality for use in the treatment of psychiatric disorders, sTMS was first assessed for the feasibility, tolerability, and patient acceptability for migraine prevention in adolescents through an open-label pilot study in 2018 (Irwin, et al.). The study was small, with only 21 participants enrolled. Participants used sTMS twice daily as a preventative measure, and followed with additional pulses for any acute episodes. A four-week run-in period was followed by a 12-week period of sTMS treatment. The authors concluded that sTMS proved feasible and acceptable but that device compliance was a challenge for adolescents, related to a 15-minute delay between pulses particularly on school days. The delay requirement was subsequently dropped from the study. The study completion rate was only 31% but increased to 88% following the protocol change. Participants used the device preventively an average of 22 to 24 days over a 28-day period of time. There were no serious adverse events. Larger, long-term higher-quality trials with established stimulation parameters are needed to determine if the use of the technology benefits the net health outcome of individuals with migraine.

Peripheral Magnetic Stimulation

Peripheral magnetic stimulation differs from electrical stimulation in that it does not require electrical currents to pass through skin and tissues. The magnetic field is believed to cause ion movement and stimulation of axons, potentially impacting cortical excitability, however, there have been no definitive conclusions regarding the mechanism of action, or creation of a standard protocol for treatment delivery. While preliminary data show that peripheral magnetic stimulation has limited complications, additional well-designed comparative studies with established protocols are needed to determine the overall efficacy and impact on health outcomes.

Transcutaneous Vagus Nerve Stimulation (tVNS)

The evidence for tVNS stimulation in individuals who have epilepsy, depression, schizophrenia, headache, or impaired glucose tolerance includes at least one randomized controlled trial and case series for some of the conditions. The RCTs are small and have various methodologic problems. Definitive efficacy of tVNS in improving outcomes among patients has not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
64555 **(E/I)**	Percutaneous implantation of neurostimulator electrode-electrode array; peripheral nerve (excludes sacral nerve)
64575 **(E/I)**	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585 **(E/I)**	Revision or removal of peripheral neurostimulator electrode array
64596 **(E/I)**	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64999 **(E/I)**	Unlisted procedure, nervous system (PNS or PNT using needle[s] or needle electrode[s]),
90867 **(E/I)***	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management *E/I when indication is headache or pain
90868 **(E/I)***	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management *E/I when indication is headache or pain
90869 **(E/I)***	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management *E/I when indication is headache or pain

Code	Description
97014	Application of a modality to one or more areas; electrical stimulation, unattended (e.g., TENS)
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes (e.g., TENS)
0766T **(E/I)**	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0767T **(E/I)**	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
0768T **(E/I)**	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0769T **(E/I)**	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
A4540 Effective 01/01/24	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Effective 01/01/24) (*Replacing K1023)*
K1023 Termed 12/31/23	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
A4541 Effective 01/01/24	Monthly supplies for use of device coded at e0733 (Effective 01/01/24) (*Replacing K1017)*
K1017 Termed 12/31/23	Monthly supplies for use of device coded at K1016
A4542 Effective 01/01/24	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist (Effective on 01/01/24) *(Replacing K1019)*
K1019 Termed 12/31/23	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
A4595	Electrical stimulation supplies, 2 lead, per month, (e.g., TENS, NMES)
A4596	Cranial electrotherapy stimulation (ces) system supplies and accessories, per month

Code	Description
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
E0720	TENS, two lead, localized stimulation
E0730	TENS, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric).
The following HCPCS code is considered investigational if not used as a TENS device:	
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
The following HCPCS codes are considered investigational:	
E0732 Effective 01/01/24 K1002 Termed 12/31/23	Cranial electrotherapy stimulation (ces) system, any type *(Effective 01/01/24) (Replacing K1002)* Cranial electrotherapy stimulation (ces) system, any type
E0733 Effective 01/01/24 K1016 Termed 12/31/23	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve *(Effective 01/01/24) (Replacing code K1016)* Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
E0734 Effective on 01/01/24 K1018 Termed 12/31/23	External upper limb tremor stimulator of the peripheral nerves of the wrist *(Effective 01/01/24) (Replacing code K1018)* (e.g., Cala Trio) External upper limb tremor stimulator of the peripheral nerves of the wrist (e.g. Cala Trio)
S8130 (**E/I)**	Interferential current stimulator, 2 channel
S8131 (**E/I)**	Interferential current stimulator, 4 channel

ICD10 Codes

Code	Description
E08.40-E08.42	Diabetes mellitus due to underlying condition with diabetic neuropathy (code range)
E09.40-E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy (code range)
E10.40-E10.42	Type 1 diabetes mellitus with diabetic neuropathy (code range)
E11.40-E11.42	Type 2 diabetes mellitus with diabetic neuropathy (code range)
E13.40-E13.42	Other specified diabetes mellitus with diabetic neuropathy (code range)
F9.0-F90.9	Attention deficit hyperactivity disorder (code range)
G13.0-G13.1	Paraneoplastic neuromyopathy and neuropathy (code range)
G25.0	Essential tremor
G43.0-G43.919	Migraine (code range)

Code	Description
G44.0-G44.89	Other headache syndromes (code range)
G54.8	Other nerve root and plexus disorders
G55	Nerve root and plexus compressions in diseases classified elsewhere
G56.00-G56.92	Carpal tunnel syndrome and mononeuropathies, upper limb (code range)
G57.00-G57.63	Lesion of sciatic nerve, lower limb (code range)
G57.60-G57.73	Causalgia of lower limb (code range)
G57.8-G59	Mononeuropathy (code range)
G63	Polyneuropathy in diseases classified elsewhere
G65.0-G65.2	Sequelae of inflammatory polyneuropathy (code range)
G89.21-G89.8	Chronic pain, not elsewhere classified (code range)
G89.4	Chronic pain syndrome
G90.50-G90.59	Complex regional pain syndrome I (code range)
M15.0-M15.9	Polyosteoarthritis (code range)
M16.0-M16.9	Osteoarthritis of hip (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M18.0-M18.9	Osteoarthritis of first carpometacarpal joint (code range)
M19.011-M19.93	Osteoarthritis, shoulder, arm and hand (code range)
M25.50-M25.579	Pain in joint (code range)
M34.83	Systemic sclerosis with polyneuropathy
M43.27	Fusion of spine, lumbosacral region
M43.28	Fusion of spine, sacral and sacrococcygeal region
M46.40-M46.49	Discitis, multiple sites (code range)
M47.10	Other spondylosis with myelopathy, site unspecified
M47.20	Other spondylosis with radiculopathy, site unspecified
M47.819	Spondylosis without myelopathy or radiculopathy, site unspecified
M47.899-M47.9	Spondylosis, unspecified (code range)
M48.00	Spinal stenosis, site unspecified
M50.00-M50.93	Cervical disc disorder with myelopathy, cervical region (code range)
M51.0 – M51.9	Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders with myelopathy

Code	Description
M53.2x7-M53.2x8	Spinal instabilities; lumbosacral and sacral sites (code range)
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies, lumbosacral sites (code range)
M54.10-M54.18	Radiculopathy (code range)
M54.2	Cervicalgia
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.50-M54.59	Low back pain (code range)
M54.6	Pain in thoracic spine
M54.81, M54.89	Other dorsalgia codes
M54.9	Dorsalgia, unspecified
M60.80-M60.9	Other myositis, specified site (code range)
M79.10-M79.18	Myalgia
M79.2	Neuralgia and neuritis, unspecified
M79.601-M79.676	Pin in limb, hand, foot, fingers and toes (code range)
M79.7	Fibromyalgia
M96.1	Postlaminectomy syndrome, not elsewhere classified
R10.0-R10.9	Abdominal and pelvic pain (code range)
R51.0-R51.9	Headache (code range)
R52	Pain, unspecified

REFERENCES

*Ahn H, et al. Feasibility and efficacy of remotely supervised cranial electrical stimulation for pain in older adults with knee osteoarthritis: a randomized controlled pilot study. J Clin Neurosci 2020 July;77:128-133.

Alam MD & Chen JDZ. Non-invasive neuromodulation: an emerging intervention for visceral pain in gastrointestinal disorders. Bioelectronic Medicine 2023; 27(9): 1-27.

Allen CB, et al. Do electrical stimulation devices reduce pain and improve function? A comparative review. Pain Ther 2023; 12:1339-1354.

Albornoz-Cabello M, et al. Effect of adding interferential current stimulation to exercise on outcomes in primary care patients with chronic neck pain: a randomized controlled trial. Clin Rehabil 2019;33(9):1458-1467.

*Barclay TH, et al. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. Journal of Affective Disorders 2014;164:171-177.

*Beltran-Alacreu H, et al. Percutaneous versus transcutaneous electrical nerve stimulation for the treatment of musculoskeletal pain. A systematic review and meta-analysis. Pain Med 2022 Aug 01; 23(8): 1387-1400.

*Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) for the treatment of rheumatoid arthritis in the hand (Review). Cochrane Database Syst Rev 2010;(7): CD004377.

*Boldt I, et al. Non-pharmacological interventions for chronic pain in people with spinal cord injury. Cochrane Database Syst Rev. 2014;11:CD009177.

*Buchmuller A, et al. Value of TENS for relief of chronic low back pain with or without radicular pain. Eur J Pain 2012 May;16(5):656-65.

Chou DE, et al. Acute migraine therapy with external trigeminal neurostimulation (ACME): A randomized controlled trial. Cephalalgia 2019;39(1):3-14.

*Chutkan, NB et al. Evidence-based clinical guidelines for multidisciplinary spine care: diagnosis and treatment of low back pain. North American Spine Society 2020 [Diagnosis and Treatment of Low Back Pain - Clinical Guideline (spine.org)] accessed 12/18/23.

Deveza & Bennell. Management of knee osteoarthritis. In: UpToDate, Hunter D (Ed), Wolters Kluwer. Accessed 12/18/23.

*Dowswell T et al. Transcutaneous electrical nerve stimulation (TENS) for pain relief in labour. Cochrane Database Syst Rev 2009;(2):CD007214.

*Dubinsky RM , et al. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology. Neurology 2010;74:173–6.

Elboim-Gabyzon M, et al. Effects of transcutaneous electrical nerve stimulation (TENS) on acute postoperative pain intensity and mobility after hip fracture: a double-blinded, randomized trial. Clin Interv Aging 2019 Oct 29;14:1841-1850.

*Gilligan C, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain 2021 Oct 21;162(10): 2486-2498.

*Gilligan C, et al. Long-term outcomes of restorative neurostimulation in patients with refractory chronic low back pain secondary to multifidus dysfunction: two-year results of the ReActiv8-B pivotal trial. Neuromodulation 2023 Jan; 26(1): 87-97.

*Gilligan C, et al. Three-year durability of restorative neurostimulation effectiveness in patients with chronic low back pain and multifidus muscle dysfunction. Neuromodulation 2023 Jan; 26(1): 98-108.

*Gilmore CA, et al. Treatment of chronic axial back pain with 60-day percutaneous medial branch PNS: Primary end point results from a prospective, multicenter study. Pain Practice 2021; 21:877-889.

Grigolon RB, et al. Editorial: Transcutaneous trigeminal nerve stimulation for children with attention-deficit/hyperactivity disorder. Journal of the American Academy of Child & Adolescent Psychiatry 2019 Apr; 58(4):392-394.

*Hershey AD, et al. Remote electrical neuromodulation for acute treatment of migraine in adolescents. Headache 2020 Nov 16; 61:310-317.

*Hurlow A, et al. Transcutaneous electrical nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev 2012;(3):CD 006276.

*Hussein HM, et al. A systematic review and meta-analysis investigating the pain-relieving effect of interferential current on musculoskeletal pain. Am J Phys Med Rehabil 2022 July;101(7)624-633.

*Isaacson SH, et al. Prospective home-use study on non-invasive neuromodulation therapy for essential tremor. Tremor Other Hyperkinet Mov 2020 Aug 14; 10: 29.

*Johnson MI, et al. Transcutaneous electrical nerve stimulation (TENS) for phantom pain and stump pain following amputation in adults. Cochrane Database Syst Rev. 2015 Aug 18;8:CD007264.

*Kamo T, et al. Repetitive peripheral magnetic stimulation for impairment and disability in people after stroke. Cochrane Database of Syst Rev. 2022:9:CD011968.

*Khadilkar A, et al. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. Cochrane Database Syst Rev 2013;(2):CD003008.

*Kim, et al. Effects of cranial electrotherapy stimulation with novel in-ear electrodes on anxiety and resting-state brain activity: A randomized double-blind placebo-controlled trial. J Affect Disord 2021 Dec 01;295:856-864.

*Kroeling P, et al. Electrotherapy for neck pain. Cochrane Database Syst Rev 2013;(8):CD004251.

*Li S, et al. Electromagnetic fields for treating osteoarthritis. Cochrane Database Syst Rev 2013;12:CD003523.

*Lim YH, et al. Effects of repetitive peripheral magnetic stimulation on patients with acute low back pain: A pilot study. Annals of Rehab Medicine 2018;42(2)229-238.

*Loh J, et al. The use of transcutaneous electrical nerve stimulation (TENS) in a major cancer center for the treatment of severe cancer-related pain and associated disability. Pain Med 2013 Feb 25.

*Martimbianco ALC, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic neck pain. Cochrane Database Syst Rev 2019 Dec 12;12(12):CD011927.

*Magis D, et al. Safety and patients' satisfaction of transcutaneous supraorbital neurostimulation (tSNS) with the Cefaly(R) device in headache treatment: a survey of 2,313 headache sufferers in the general population. J Headache Pain 2013;14:95.

*McGough JJ, et al. Double-Blind, Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry 2019;58(4):403–411.

Mori N, et al. Analgesic effects of repetitive transcranial magnetic stimulation at different stimulus parameters for neuropathic pain: a randomized study. Neuromodulation 2022 Jun;25(4):520-527.

*Plaza-Manzano G, et al. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. Eur J Pain Jul 2020;24(6):1023-1044.

*Gibson, W, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev 2019;(4):CD011890.

Gil-Lopez, et al. External trigeminal nerve stimulation for drug resistant epilepsy: A randomized controlled trial. Brain Stimulation 2020 Jun;(13):1245-1253.

*Irwin SL, et al. Transcranial magnetic stimulation for migraine prevention in adolescents: a pilot open-label study. Headache 2018 May;58(5):724-731.

*Pahwa R, et al. An acute randomized controlled trial of noninvasive peripheral nerve stimulation in essential tremor. Neuromodulation 2019; 22:537-545.

Price L, et al. A meta-analysis of cranial electrotherapy stimulation in the treatment of depression. Journal of Psychiatric Research 2021;135:119-134.

*Pelland L, et al. Electrical stimulation for the treatment of rheumatoid arthritis (Review). Cochrane Database Syst Rev 2010;(7): CD003687.

Plaza-Manzano, et al. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. European Journal of Pain 2020 Mar;24:1023-1044

Resende L, et al. Meta-analysis of transcutaneous electrical nerve stimulation for relief of spinal pain. Eur J Pain 2018 Apr;22(4):663-678.

*Rutjes AWS, et al. Transcutaneous electrostimulation for osteoarthritis of the knee. Cochrane Database Syst Rev 2010;(1): CD002823.

Sayilir S. The short-term effects of TENS plus therapeutic ultrasound combinations in chronic neck pain. Complement Ther Clin Pract 2018 May;31:278-281.

*Schoenen J, et al. Migraine prevention with a supraorbital transcutaneous stimulator: a randomized controlled trial. Neurology 2013;80(8):697-704.

*Simpson PM, et al. Transcutaneous electrical nerve stimulation for relieving acute pain in the prehospital setting: a systematic review and meta-analysis of randomized-controlled trials. Eur J Emerg Med Feb 2014;21(1):10-17.

*Strand N, et al. Evidence-based clinical guidelines from the American Society of Pain and Neuroscience for the use of implantable peripheral nerve stimulation in the treatment of chronic pain. Journal of Pain Research 2022 Aug;15:2483-2504.

Tauben D & Stacey BR. Approach to the management of chronic non-cancer pain in adults. In: UpToDate, Fishman S (Ed), Wolters Kluwer. Accessed 11/27/23.

Thakkar B, et al. Prolonged continuous theta burst stimulation increases motor corticospinal excitability and intracortical inhibition in patients with neuropathic pain: an exploratory, single-blinded, randomized controlled trial. Neurophysiol Clin 2023 Aug;53(4): Epub August 2023.

Toma O, et al. PROSPECT guideline for rotator cuff repair surgery: systematic review and procedure-specific postoperative pain management recommendations. Anaesthesia 2019 Oct;74(10):1320-1331.

*Vance CG, et al. Effects of transcutaneous electrical nerve stimulation on pain, pain sensitivity and function in people with knee osteoarthritis: a randomized controlled trial. Phys Ther 2012 Jul;92(7):898-910.

*van Middlelkoop M, et al. A systematic review of the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. Eur Spine J 2011 Jan;(1):19-39.

*Walsh DM et al. Transcutaneous electrical nerve stimulation for acute pain. Cochrane Database Syst Rev 2009;(2):CD006142.

*Weiner DK, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain 2008 Nov;140(2):344-357.

*White PF et al. Percutaneous Neuromodulation therapy: does the location of electrical stimulation effect the acute analgesic response? Anesth Analg 2000 Oct; 91:949-954.

Wu LC, et al. Literature review and meta-analysis of transcutaneous electrical nerve stimulation in treating chronic back pain. Reg Anesth Pain Med 2018 May 43(4):425-433.

*Wu WJ, et al. A double-blind, randomized, sham-controlled study of cranial electrotherapy stimulation as an add-on treatment for tic disorders in children and adolescents. Asian J Psychiatr 2020 Jun;51:101992.

*Yarnitsky D, et al. Remote electrical neuromodulation (REN) relieves acute migraine: a randomized, double-blind, placebo-controlled, multicenter trial. Headache J Head Face Pain 2019;59:1240–52.

Yu B, et al. Noninvasive brain stimulation does not improve neuropathic pain in individuals with spinal cord injury: evidence from a meta-analysis of 11 randomized controlled trials. Am J Phys Rehabil 2020;99:811-820.

*Zizic TM et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. J Rheumatol 1995 Sep;22(9):1757-1761.

KEY WORDS

Bionicare, Electrical nerve stimulation, Electrotherapy, IFS, Percutaneous neuromodulation therapy, Transcutaneous nerve stimulation, Neuromodulation, Remote electrical neuromodulation, Nerivio, Cranial electrical stimulation, Alpha Stim, Trigeminal Nerve Stimulation, Peripheral magnetic stimulation.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) and a Local Coverage Determination (LCD) for TENS units. Please refer to the following NCD and LCD websites for Medicare Members:

There is currently a Local Coverage Determination (LCD L33802) for Transcutaneous Electrical Nerve Stimulators: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33802&ver=35&CntrctrSelected=137*1&Cntrctr=137&s=41&DocType=Active&bc=AggAAAIAgAAA&= accessed 03/08/24.

There is currently a National Coverage Determination (NCD) for TENS units for Acute Post-Operative Pain (NCD 10.2). Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=145&ncdver=2&bc=AAAAgAAAAAAA& accessed 12/28/23.

There is currently a National Coverage Determination (NCD) for TENS units for Chronic Low Back Pain (NCD 160.27). Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=354&ncdver=1&bc=AgAAgAAAAAAAAA%3d%3d& accessed 12/28/23.