MEDICAL POLICY

Medical Policy Title	**Electrical Stimulation as a Treatment for Pain and Other Medical Conditions**
Policy Number	**1.01.55**
Current Effective Date	**November 20, 2025**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Transcutaneous Electrical Nerve Stimulation (TENS)

I. TENS devices are considered **medically necessary** when **ALL** of the following criteria are met:
   - A. U.S. Food and Drug Administration (FDA) approved;
   - B. The device is utilized for the treatment of pain;
   - C. Symptoms persist for greater than three (3) months;
   - D. There has been a failure of physical therapy, osteopathic manipulative therapy, or chiropractic therapy;
   - E. Failure of medications (e.g., simple analgesics, nonsteroidal anti-inflammatory drugs (NSAIDS) or opioids); **and**
   - F. A 30-day trial period has demonstrated efficacy of the treatment.

II. Form-fitting TENS conductive conducting garments utilized for the delivery of TENS therapy are considered **medically necessary** when **ALL** of the following criteria are met:
   - A. U.S. FDA approved;
   - B. When policy statement one (1) criteria are met;
   - C. The nerve supply to the stimulated area is intact; **and**
   - D. At least **ONE** of the following criteria apply:
     1. 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;
     2. The stimulation site is not accessible with standard electrodes, adhesive tape or lead wires; **or**
     3. Skin or other medical condition exists that would prevent the adherence of standard electrodes, tapes or lead wires.

III. TENS is 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;
H. Neck pain.

Neuromuscular Electrical Stimulation (NMES)

IV. NMES is considered **medically necessary** for disuse muscle atrophy when **ALL** of the following criteria are met:
   A. Nerve supply to the muscle is intact (including brain, spinal cord and peripheral nerves); **and**
   B. For non-neurological reasons (e.g., casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip or knee replacement surgery) (until orthotic training begins).

V. NMES is considered **not medically necessary** for **ALL** other indications.

Functional Electrical Stimulation (FES)

VI. FES is considered **not medically necessary** for **ANY** of the following indications including but not limited to:
   A. For ambulation in patients with spinal cord injury:
   B. For stroke rehabilitation;
   C. Gait training.

VII. All other forms of stimulation are considered **investigational** for **ALL** indications, including the following:
   A. Afferent Patterned Stimulation Therapy for Essential Tremor; (e.g., Cala One, Cala Trio);
   B. Auricular Electrostimulation; (e.g., IB-Stim, NSS-2 Bridge device, P-Stim);
   C. Cranial Electrical Stimulation; (e.g., Alpha Stim-AID, Carvella, CES Ultra);
   D. Electromagnetic Stimulators; (e.g., OrthoCor Active Knee System, and RS-4i sequential stimulator);
   E. External Trigeminal Nerve Stimulation (eTNS) (e.g., Monarch);
   F. Interferential Stimulation; (e.g., RS 4i Sequential Stimulator, Empi IF 3Wave);

G. Multiple Modality Delivery Stimulation;

H. Percutaneous Electrical Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT);

I. Peripheral Magnetic Stimulation (e.g., Axon Therapy, MagVenture Pain Therapy);

J. Peripheral Nerve Stimulation (PNS)**:**

1. Permanent PNS Systems (e.g., Moventis PNS, StimQ, Nalu);
2. Temporary PNS System (e.g., SPRINT);
3. Electro Magnetic Transcutaneous Peripheral Nerve Stimulator (mPNS) (Axon Therapy devices, MagVenture Pain Therapy) for chronic diabetic neuropathy;

K. Pulsed Electrical Stimulators (PES), including BioniCare when used to facilitate repair of cartilage in patient with arthritis; (e.g., SoftPulse, MedRelief ST Series, and Jstim1000);

L. Remote Electrical Neuromodulation Stimulation (REN) (e.g., Nerivio);

M. Restorative Neurostimulation Stimulation;

N. Targeted Electromagnetic Field (e.g., SofPulse);

O. Transcutaneous Electrical Joint Stimulation (TEJSD) for the treatment of joint pain associated with arthritis;

P. Transcutaneous/Non-Implantable Vagus Nerve Stimulation (tVNS);

Q. Transcutaneous Supraorbital Neurostimulation; (e.g., Cefaly).

Repair and Replacement

VIII. Repair and/or replacement of medically necessary electrical stimulation devices 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 implantation/initiation; manufacturer warranty information,
2. Attestation that the patient has been compliant with the use of device, and
3. Will continue to benefit from the use of device;

AND ONE OF THE FOLLOWING APPLY:

B. Repair of the currently used device when **ALL** of the following are met:

1. It is no longer functioning adequately,
2. Inadequate function interferes with activities of daily living, and

3. Repair is expected to make the equipment fully functional (as defined by manufacturer); OR

C. Replacement of the currently used device when the following are met:

1. It is no longer functioning adequately,

AND EITHER

2. Has been determined to be non-repairable, or

3. The cost of the repair is in excess of the replacement cost;

OR

D. Replacement of the currently used device when BOTH of the following are met:

1. There is documentation that a change in the patient's condition makes the present unit non-functional, and

2. Improvement is expected with a replacement unit.

IX. The replacement of properly functioning electrical stimulation devices 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.

X. 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**.

RELATED POLICIES

Corporate Medical Policy

1.01.07 Oral Appliance for the Treatment of Obstructive Sleep Apnea

1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

7.01.41 Surgical Management of Sleep Disorders

8.01.22 Tibial Nerve Stimulation (TNS) for Voiding Dysfunction

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

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.

III. The correct CPT code to use for percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., CPT code 64553 to 64561) are not appropriate, because PENS and PNT use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PENS and PNT are not implanted, so CPT code 64590 is also not appropriate.

DESCRIPTION

Electrical stimulation (Estim) is a technique that uses low level electrical currents to stimulate muscles or nerves for therapeutic purposes. These devices and treatments are used in various medical and physical therapy application. The 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.

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., is 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.

TENS for the Treatment of Arthritis

The BioniCare Bio-1000 stimulator (VQ OrthoCare) delivers 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 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 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. The OrthoCor Knee System 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. the SofPulse (also called Torino II, 912-M10, and Roma; Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing 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.

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).

Neuromuscular Electrical Stimulation (NMES) /Functional Electrical Stimulation (FES)

NMES is a form of treatment that uses a device that transmits an electrical impulse to activate muscle groups by way of electrodes. NMES is proposed to promote neuromuscular re-education, improve motor unit recruitment, and prevent or diminish muscle atrophy. NMES is typically used as a component of a comprehensive rehabilitation program. Compared to TENS, NMES delivers a stronger current with a wider pulse width. The stimulator device is classified as durable medical equipment. NMES can be referred to as functional electrical stimulation (FES), functional neuromuscular stimulation (FNMS), or electromyography (EMG) triggered neuromuscular stimulation.

Functional electrical stimulation involves the use of an orthotic device or exercise equipment with microprocessor controlled electrical muscular stimulation. FES devices are being developed to restore function and improve health in individuals with damaged or destroyed nerve pathways (e.g., spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy). It attempts to replace stimuli from destroyed nerve pathways with computer-controlled sequential electrical stimulation of muscles through surface or implanted electrodes. The goal is to enable patients with spinal cord injury (SCI) or stroke to function independently or at least maintain muscle tone and strength.

Surface or percutaneous devices for upper extremity FES (e.g., H200 Wireless Hand Rehabilitation System) combine a wrist/hand orthosis with integrated surface electrodes to activate muscles of the paralyzed forearm and hand. Upper extremity surface FES devices may be most effective when used soon after spinal cord injury, during the acute phase of rehabilitation.

Threshold electrical stimulation (TES) uses surface electrodes to stimulate the muscle when the patient is in a resting state. It is intended to increase muscle strength and joint mobility, leading to improved voluntary motor function.

Parastep I is a surface FES device intended to allow patients with lower extremity paralysis to stand and walk short distances.

The WalkAide system is a FES device that improves the walking ability of people suffering from foot drop. WalkAide uses sensor technology to analyze the movement of the leg and foot, sending electrical signals to the peroneal nerve which activates the muscles to raise the foot at the appropriate time during the step cycle.

Implanted FES devices (e.g., the Freehand System) devices incorporate surgically implanted

stimulation electrodes, an implanted stimulator, and an external power supply. A shoulder position sensor mounted on the chest and shoulder translates small shoulder movements into a control signal. Use of these devices requires intensive and lengthy training by rehabilitation specialists.

MicroVas is a noninvasive electrical stimulator that causes muscles contraction and relaxation cycles. It is used to treat small vessel disease and neuropathy in the feet and ankles. The MicroVas stimulator is supposed to increase blood flow, tissue oxygenation, promote lymphatic drainage, and induce involuntary exercise. However, it has not been proven for this purpose. MicroVas therapy was developed originally by the U.S. Military to treat hypothermia in Navy Seals.

VitalStim Therapy is a type of neuromuscular electrical stimulation in which a small current is passed through external electrodes placed on the neck to stimulate inactive or atrophied swallowing muscles. With repeated therapy, throat muscles are reported to be re-trained, and the patient is progresses to an optimum level of swallow function.

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 or injection therapy.

The Moventis PNS (Micron Medical Corporation) received FDA approval 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 involves a 3-step process: wear experience, therapy trial, and permanent implantation. The treatment involves the initial use of adhesive clips and nonfunctioning Therapy Discs to determine future stimulation location and comfort level, followed by a temporary trial of the implanted leads, prior to permanent implantation. It is used for the management of chronic pain.

The SPRINT peripheral nerve stimulation system (SPR Therapeutics, Inc.) is 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.

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.

Restorative Neurostimulation Therapy

The ReActiv8 (Mainstay Medical) device 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.

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).

External Trigeminal Nerve Stimulation (eTNS)

The Monarch eTNS system, (NeuroSigma) is 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.

Transcutaneous Supraorbital Neurostimulation

The Cefaly device (CEFALY Technology) received FDA approval 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.

Remote Electrical Neuromodulation (REN)

REN is a nonpharmacologic abortive treatment of migraine. The Nerivio device (Theranica) was cleared by the FDA for patients aged 12 years and above. 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.

Afferent Patterned Stimulation Therapy for Essential Tremor

The Cala Trio (Cala Health) is an external upper limb tremor stimulator. 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.

Cranial Electrical Stimulation (CES)

CES is also known as cranial electrotherapy, transcranial electrical stimulation or electrical stimulation therapy. The most common CES device in the United States, is the Alpha Stim products. Alpha Stim-AID, and Alpha-Stim M 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.

Peripheral Magnetic Stimulation (PMS)

Peripheral magnetic stimulation (PMS), or transcutaneous magnetic stimulation, is a non-invasive method of delivering a rapidly pulsed, high-intensity magnetic field to the periphery other than the brain.

Axon Therapy (NeuraLace Medical, Inc.) utilizes a figure-8 shaped coil to deliver focused magnetic pulses to damage 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) are intended for use in the hospital and clinics.

Transcutaneous/Non-Implantable 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.

GammaCore-S (electroCore LLC) is a noninvasive vagus nerve stimulation device 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 additional approval for 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.

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 combination devices.

Auricular Electrostimulation

Electrical stimulation of auricular acupuncture points, or auricular electrostimulation, involves the stimulation of acupuncture points on the ear. Auricular electrostimulation has been proposed for the treatment of a variety of conditions, including pain, depression, and anxiety. Devices have been developed that provide electrical stimulation to auricular acupuncture sites over a period of several days.

The P-Stim (NeuroScience Therapy Corporation) is a single-use, miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify three auricular acupuncture points. The P-Stim device connects to three inserted acupuncture needles with caps and wires. The device is pre-programmed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

The E-pulse, or Electro Acupuncture device, is a microprocessor-controlled, battery-powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96-hour period.

Auricular PENFS is a variation of PENS in that it uses a low-frequency electrical current to stimulate the skin and underlying tissues in a general area of pain rather than targeting a specific nerve. PENFS devices are thought to work by sending electrical stimulation of peripheral cranial neurovascular bundles in the external ear to help modulate central pain pathways, however, the exact mechanism responsible for the analgesic effects remains unknown. PENFS involves a nonimplantable device that stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal and neuropathic pain conditions, and patients with opioid withdrawal.

The NSS-2 Bridge device (Innovative Health Solutions, Inc.) is a small electrical nerve stimulator placed behind the ear that emits electrical pulses to stimulate branches of certain cranial nerves, which may provide relief from opioid withdrawal symptoms. This device was approved for use in reducing the symptoms of opioid withdrawal.

The IB-Stim (Innovative Health Solutions, Inc.) is a disposable, battery-powered, percutaneous electrical nerve field stimulator (PENFS) system placed behind the ear. The device has four percutaneously placed electrodes (three frontal and one dorsal) applied to auricular areas innervated by branches of four cranial nerves (CN V, VII, IX, and X). It is intended use are for patients 11-18 years old with functional abdominal pain disorders (FAPD) associated with irritable bowel syndrome (IBS). The device is for use 120 hours per week for three consecutive weeks.

SUPPORTIVE LITERATURE

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. 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.

Johnson et al (2022) conducted a systematic review and meta-analysis that evaluated the effectiveness and safety of TENS for pain relief in adults. Researchers analyzed data from 381 randomized controlled trials involving 24,532 participants. The findings showed that TENS significantly reduced pain intensity during or immediately after treatment compared to placebo, with moderate-certainty evidence. It also showed benefits over standard pharmacological and non-pharmacological treatments, though with low-certainty evidence due to small sample sizes and imprecision. The type of pain and study methodology did not significantly affect outcomes. Adverse events were infrequently reported, generally mild, and similar to those in comparison groups. Overall, TENS appears to be a safe and moderately effective method for short-term pain relief.

Peripheral Nerve Stimulation

Lin et al (2024) conducted a systematic review and meta-analysis of randomized controlled trials. The authors investigated the effectiveness of peripheral nerve stimulation (PNS) has on pain and improvement in function on post operative lower-limb orthopedic patients. Data was used from eight randomized controlled trials involving 633 patients. While PNS did not significantly reduce pain intensity or improve functional outcomes such as range of motion and length of hospitalization, it did lead to a marginally significant reduction in analgesic consumption. These findings suggest that although PNS may offer some benefit in reducing the need for pain medication, its overall clinical efficacy remains uncertain. The authors recommend future research with larger sample sizes, longer follow-up periods, and varied stimulation parameters to better assess its potential.

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 et al (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. 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 sub study 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.

Neuromuscular and Functional Electrical Stimulation

Sajiki-Ito et al (2024) conducted a retrospective study to investigate the effects of inpatient rehabilitation on muscle mass and physical performance in older adults following hip fracture surgery. Seventeen patients with a mean age of 85 years underwent a rehabilitation program that included exercises for joint mobility, muscle strengthening, gait training, early mobilization, and neuromuscular electrical stimulation. Over six weeks, lower limb muscle mass significantly increased, while upper limb muscle mass and body weight decreased. Total muscle and fat mass remained stable. Grip strength was maintained, and knee extension strength improved on both the healthy and affected sides. All patients showed better ability to perform daily activities, though only about half regained their pre-injury walking ability. The findings suggest that targeted rehabilitation can effectively enhance lower limb muscle mass and functional recovery after hip fracture surgery.

Conley et al (2021) conducted a systematic review aimed to evaluate how different neuromuscular electrical stimulation (NMES) parameters affect quadriceps strength recovery following knee surgery. Researchers searched four major databases and included eight randomized controlled trials (RCTs) that met strict criteria, such as reporting specific NMES parameters and quadriceps strength outcomes. The study consisted of 17 patients with a mean age of 84 years. Postoperative factors measured after one and six weeks were: muscle mass, body weight, fat mass, grip strength, bilateral knew extension strength, ability to walk and ability to perform activities of daily living (ADLs). Results showed lower limbs skeletal muscle mass increased (median 4.8 kg to 4.9 kg), while upper limbs skeletal muscle mass and body weight decreased (median 1.2 kg to 1.1 kg), (median 46.8 kg to 45.5 kg). Total skeletal muscle mass and fat mass remained unchanged. Grip strength was maintained, and knee extension muscle strength on the healthy and affected sides increased (healthy side median 10.7 kgf to 13.7 kgf; affected side median 5.5 kgf to 9.5 kgf). Ability to perform ADLs improved amongst all patients. Patients regained their pre-injury walking ability (52.9%). Optimal outcomes were associated with NMES applied within the first two weeks post-surgery, using a frequency of ≥50 Hz, maximum tolerable intensity, biphasic current, large electrodes, and a duty cycle ratio of 1:2 to 1:3 with a 2–3 second ramp time.

There is insufficient data to demonstrate that FES results in improved net health outcomes. Data is insufficient regarding whether patients remain compliant and committed with long-term use of the devices (Parastep I, the Neuro Control Freehand System, the Ness H200 Hand Rehabilitation System, the Ness L300 Foot Drop System, G. Estim FES, and the WalkAide System).

No published studies of the MicroVas device were identified. Micro Vas therapy has been around since the late 1980s. It was originally used to treat hypothermia in Navy Seals who experienced the negative effects of extreme temperatures. Over time, Micro Vas therapy evolved into a treatment for neuropathy and other painful conditions, especially those that affect the extremities.

To date, there have been very few studies of surface electrical stimulation to the neck for swallowing that support the efficacy of VitalStim. These studies have small sample size and report mixed results.

There is insufficient evidence in the peer reviewed literature to conclude that electrical stimulation is effective in the treatment of dysphagia. Stimulators have not been studied in pregnant women or patients with seizures and balance disorders.

Restorative Neurostimulation Therapy

ReActiv8 system FDA approval 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.

Interferential Stimulation

Hussien et al (2021) conducted a meta-analysis including 19 trials, (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

Schoenen et al (2013) reported the results from the Prevention of Migraine (PREMICE) trial, a multi-center, randomized, sham controlled trial. They assessed the efficacy and safety of supraorbital transcutaneous neurostimulation (STNS) in migraine prophylaxis with the Cefaly device. The trial consisted 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

Yarnitsky et al (2019) conducted a vendor- funded double blind RCT from 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 et al (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 (2019) 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 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.

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.

Auricular Electrical Stimulation

Kovacic et al (2017) conducted an RCT comparing the Neuro-Stim PENFS device with a sham device in adolescent patients with abdominal pain-related functional gastrointestinal disorders including IBS. Patients 11 to 18 years of age with abdominal pain (pain score ≥3 on an 11-point scale) occurring at least twice weekly for at least two (2) months were included. The devices were worn for five (5) days each week for four (4) weeks. Baseline medications were continued except for antispasmodics which were not allowed during the study period. Enrolled patients were primarily female (91%) and White (90%). Pain, as measured on the Pain Frequency-Severity-Duration (PFSD), was the primary outcome. The PFSD scale incorporates several aspects of the pain experience and is generally calculated over 14 days but was modified as a weekly score in this trial with a high composite score

of 70. Both "worst pain" and median PFSD composite scores were better with PENFS than placebo. The Symptom Response Scale (-7 to +7 [with negative scores as worse and positive scores as better]) was used to assess the overall symptoms. Although the authors reported statistically significantly improved scores with the Neuro-Stim device at 3 weeks, numerical differences between groups were small. Longer-term pain scores obtained at a median of 9.2 weeks after treatment remained improved from baseline in the active treatment group with a decrease of composite PFSD scores of -8.4 compared with 0.0 in the sham group. Adverse events including ear discomfort and adhesive allergy were similar between groups. The study is limited by the small sample size, the heterogeneous population of gastrointestinal disorders, the lack of bowel habit measurement, and the short duration of follow-up. Krasaelap et al (2020) evaluated a subgroup of 50 patients with IBS from the Kovacic et al (2017) RCT. At three (3) weeks there were more responders with the active treatment (response defined as ≥30% reduction in worst abdominal pain) than with the sham device. At the extended follow-up (8-12 weeks), the percentage of responders was similar between groups (32% vs. 18%; p=.33).

PROFESSIONAL GUIDELINE(S)

The American Society of Pain and Neuroscience 2022 Clinical Guidelines for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain stated:

Facial Pain

- “Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average effect size for relief of migraine symptoms is modest to moderate (Level I, Grade B).”
- “There is insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain (Level II-3, Grade C).”

Upper Extremities

- “PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain. (Level I, Grade B)”
- “PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief. (Level II-2, Grade B)”

Lower Back and Trunk

- “Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone (Level I, Grade B).”
- “There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain (Level II-2, Grade B).”

- "There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia (Level III, Grade C)."

Lower Extremities

- "PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief (Level I, Grade B)."
- "PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief (Level I, Grade B). (Strand 2022)."

The North American Spine Society released Clinical Guidelines for Multidisciplinary Spine Care in the Diagnosis and Treatment of Low Back Pain in 2020 stated:

- "For individuals undergoing treatment for lower back pain, there is conflicting evidence that TENS results in improvement in pain or function at short- to medium term follow-up. Grade of Recommendation: I" (Kreiner 2020).

According to the Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness publication on Non-Invasive Treatments for Low Back Pain (2016), additional evidence demonstrates that TENS is not effective versus sham TENS. Effectiveness of TENS was previously classified as insufficient, and the strength of evidence remains low because of methodological limitations in the trials and imprecision. Evidence on harms associated with TENS was limited but suggests an increased risk of skin site irritation without an increased risk of serious adverse events (AHRQ, 2016).

The American College of Physician's Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain Clinical Practice Guideline (2017), stated that evidence was insufficient to determine the effectiveness of transcutaneous electrical nerve stimulation (TENS).

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 29]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Oct 29]

Listing of FDA Approved Devices (not an all-inclusive list)

- IB Stim device (2025)
- MagVenture Pain Therapy devices (Tonika Elektronik A/S) (2023)
- Nerivio device (Theranica) (2023)

- Nalu Neurostimulation (Nalu Medical, Inc.) system (2020)
- Moventis PNS (Micron Medical Corporation) (2020)
- ReActiv8 (Mainstay Medical) device (2020)
- Cala Trio (Cala Health) (2021)
- Axon Therapy (NeuraLace Medical, Inc.) (2021)
- Monarch eTNS System, (NeuroSigma) (2019)
- Cranial Electrotherapy Stimulators (CES) (2019)
- SPRINT Peripheral Nerve Stimulation System (SPR Therapeutics, Inc.) (2017)
- GammaCore-S (electroCore LLC) (2017)
- Cefaly Device (CEFALY Technology) (2014)
- E-pulse (2009)
- OrthoCor Knee System (2009)
- SofPulse (also called Torino II, 912-M10, and Roma; Ivivi Health Sciences, renamed Amp Orthopedics) (2008)
- P-Stim (2006)
- BioniCare Bio-1000 Stimulator (VQ OrthoCare) (1997)

Listing of FES Devices FDA approved (not an all-inclusive list)

Hand Stimulators:

- MyndMove System (MyndTec) (2017)
- NESS H200 (previously Handmaster) (Bioness) (2001)

Foot Drop Stimulators:

- EvoWalk 1.0 (Evolution Devices Inc) (2023)
- L100 Go (Bioness) (2020)
- WalkAide System (Innovative Neurotronics [formerly NeuroMotion]) (2005)

Leg Cycle Ergometer:

- Myocycle Home (Myolyn) (2017)
- ERGYS (TTI Rehabilitation Gym) (Therapeutic Alliances) (1984)

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than

policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64555 (E/I)	Percutaneous implantation of neurostimulator electrode-electrode array; peripheral nerve (excludes sacral nerve)
64567 (E/I) Effective 01/01/26 0720T (E/I) Termed 12/31/25	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (Effective 01/01/26) (Replacing code 0720T) Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (e.g., IB-Stim system)
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
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
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]),
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)
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

Code	Description
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)
0783T (E/I)	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment

HCPCS Codes

Code	Description
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
A4541	Monthly supplies for use of device coded at E0733
A4542	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
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient

Code	Description
C9807 (E/I)	Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023
E0720	TENS, two lead, localized stimulation
E0721 (E/I)	Transcutaneous electrical nerve stimulatory, stimulates nerves in the auricular region
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).
E0732 (E/I)	Cranial electrotherapy stimulation (CES) system, any type
E0733 (E/I)	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
E0734 (E/I)	External upper limb tremor stimulator of the peripheral nerves of the wrist (e.g., Cala Trio)
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0762 (E/I)	Transcutaneous electrical joint stimulation device system, includes all accessories
E0764 (NMN)	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0769 (NMN)	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
E0770 (NMN)	Functional neuromuscular stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
G0281 (NMN)	Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

Code	Description
G0282 (NMN)	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
G0283 (NMN)	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
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)
F10.10-F10.99 (E/I)	Alcohol related disorders (code range)
F11.10-F11.99 (E/I)	Opioid related disorders (code range)
F12.10-F12.99 (E/I)	Cannabis related disorders (code range)
F13.10-F13.99 (E/I)	Sedative, hypnotic, or anxiolytic related disorders (code range)
F14.10-F14.99 (E/I)	Cocaine related disorders (code range)
F15.10-F15.99 (E/I)	Other stimulant related disorders (code range)
F16.10-	Hallucinogen related disorders (code range)

Code	Description
F16.99 (E/I)	
F17.200-F17.299 (E/I)	Nicotine dependence (code range)
F18.10-F18.99 (E/I)	Inhalant related disorders (code range)
F19.10-F19.99 (E/I)	Other psychoactive substance related disorders (code range)
G43.001-G43.019	Migraine without aura (code range)
G43.101-G43.419	Polyneuropathy in diseases classified elsewhere
G43.701-G43.719	Sequelae of inflammatory polyneuropathy (code range)
G43.B0-G43.B1	Chronic pain, not elsewhere classified (code range)
G43.801-G43.919	Chronic pain syndrome
G44.1	Complex regional pain syndrome I (code range)
G44.201-G44.209	Polyosteoarthritis (code range)
G44.211-G44.219	Osteoarthritis of hip (code range)
G44.221-G44.229	Osteoarthritis of knee (code range)
G44.301-G44.309	Osteoarthritis of first carpometacarpal joint (code range)
G44.321-G44.329	Osteoarthritis, shoulder, arm and hand (code range)
G46.0-G46.8 (NMN)	Pain in joint (code range)

Code	Description
G50.0-G50.9	Systemic sclerosis with polyneuropathy
G51.2-G51.9	Fusion of spine, lumbosacral region
G56.00-G56.03	Fusion of spine, sacral and sacrococcygeal region
H92.01-H92.09	Otalgia (code range)
I67.2 (NMN)	Cerebral atherosclerosis
I67.81-I67.82 (NMN)	Other specified cerebrovascular diseases (code range)
I67.89 (NMN)	Other cerebrovascular disease
I67.9 (NMN)	Cerebrovascular disease, unspecified
I68.0 (NMN)	Cerebral amyloid angiopathy
I68.8 (NMN)	Other cerebrovascular disorders in diseases classified elsewhere
K58.0-K58.9 (E/I)	Irritable bowel syndrome (code range)
K91.0	Vomiting following gastrointestinal surgery
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-M19.079	Primary osteoarthritis (code range)
M19.111-M19.179	Post-traumatic osteoarthritis (code range)
M19.211-M19.279	Secondary osteoarthritis (code range)
M19.90-	Osteoarthritis, unspecified site (code range)

Code	Description
M19.93	
M25.50-M25.579	Pain in joint (code range)
M26.621-M26.629	Arthralgia of temporomandibular joint (code range)
M43.26-M43.28	Fusion of spine (code range)
M43.8x6-M43.8x9	Other specified deforming dorsopathies (code range)
M51.16-M51.17	Intervertebral disc disorders with radiculopathy (code range)
M53.1	Cervicobrachial syndrome
M53.2x7	Spinal instabilities, lumbosacral region
M53.2x8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies (code range)
M53.9	Dorsopathy, unspecified
M54.06-M54.09	Panniculitis affecting regions of neck and back (code range)
M54.16-M54.18	Radiculopathy (code range)
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.5	Low back pain
M60.80-M60.9	Other myositis (code range)

Code	Description
M62.830	Muscle spasm of back
M77.10-M77.12	Lateral epicondylitis (code range)
M79.0	Rheumatism, unspecified
M79.10-M79.18	Myalgia (code range)
M79.2	Neuralgia and neuritis, unspecified
M79.601-M79.676	Pain in limb, hand, foot, fingers and toes (code range)
R10.0-R10.9	Abdominal and pelvic pain (code range)
R51.0-R51.9	Headache (code range)
R52	Pain, unspecified

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Transcutaneous Electrical Nerve Stimulators (TENS) (LCD L33802) [accessed 2025 Oct 20]

Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (NCD 10.2) [accessed 2025 Oct 20]

Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (NCD 160.27) [accessed 2025 Oct 20]

Neuromuscular Electrical Stimulation (NMES) (NCD 160.12) [accessed 2025 Oct 20]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

11/24/24, 11/20/25

Date	Summary of Changes
12/31/25	• Code edit; Added code 64567, replacing code 0720T.
12/12/25	• Policy edit; removed neuromuscular electrical stimulation from the list of investigational devices.
11/20/25	• Annual Review; removed transcranial magnetic stimulation (TMS) content as it is covered on the TMS medical policy. Neuromuscular Electrical Stimulation

	(NMES) changed to medically necessary for disuse muscle atrophy.
01/01/25	• Summary of changes tracking implemented.
11/24/24	• Original effective date