LifeWise
Health Plan of Washington

MEDICAL POLICY – 1.01.507

Electrical Stimulation Devices

BCBSA Ref. Policy: 1.01.09

Effective Date:	Dec. 1, 2024
Last Revised:	Nov. 12, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

1.01.24	Interferential Current Stimulation
1.01.27	Electrical and Electromagnetic Stimulation for the Treatment of Arthritis
2.01.57	Electrostimulation and Electromagnetic Therapy for Treating Wounds
2.01.106	Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome
7.01.69	Sacral Nerve Neuromodulation/Stimulation
7.01.125	Occipital Nerve Stimulation
7.01.139	Peripheral Subcutaneous Field Stimulation
7.01.171	Remote Electrical Neuromodulation for Migraines
7.01.522	Gastric Electrical Stimulation
7.01.574	Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain and Other Conditions
7.01.588	Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
7.01.593	Vagus Nerve Stimulation
8.01.540	Cranial Electrotherapy Stimulation and Auricular Electrostimulation
8.03.01	Functional Neuromuscular Electrical Stimulation

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Introduction

When muscles can't be used after an injury or surgery, there's a risk that the tissue will deteriorate or waste away. This is known as disuse atrophy. Neuromuscular electrical stimulation (NMES) is a way to keep muscles active so they won't atrophy. In NMES, an electrode — a patch attached to skin that can transmit electrical signals into the body — is placed over the muscles to be stimulated. A device then sends an electrical signal to the electrode and through the skin. The muscle contracts. This contraction keeps the muscles active when they otherwise wouldn't be. This policy describes when NMES may be considered medically necessary. Other types of

electrical stimulation have been proposed to try to improve function or relieve pain. These are considered investigational (unproven). There's not enough evidence to show they are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Services eligible for reimbursement (E0745)	**Use of a neuromuscular electrical stimulator (NMES) via an open loop system, including but not limited to the RS 4m and RS 2m, may be considered medically necessary for disuse atrophy when the nerve supply to the muscle is intact and the individual has any of the following non-neurological causes for disuse atrophy:** • Previous casting or splinting of a limb (arm or leg) • Contractures due to soft tissue scarring from burns • Previous major knee surgery (e.g., total knee replacement), when there is a failure to respond to physical therapy • Recent hip replacement surgery (up until the time physical therapy begins) **A conductive garment may be needed when a member meets criteria for treatment with a neuromuscular electrical stimulation device (NMES) and has one of the following medical indications:** • The treatment site is large and using a large number of standard electrodes is impractical • There are multiple large treatment sites on the body that make using standard electrodes impractical • The treatment site is hard to reach using standard electrodes and lead wires

Service	Medical Necessity
	• The member has a skin sensitivity that precludes use of standard electrodes, adhesive tape or lead wires **Note:** Functional neuromuscular electrical stimulators (closed loop systems) are addressed in a separate policy (see **Related Medical Policies**).

Service	Investigational
Services not eligible for reimbursement	**Galvanic or high-voltage galvanic stimulation is considered investigational for the treatment of chronic pain and for all other indications (e.g., FastStart HVPC) (E1399)** **H-wave stimulation is considered investigational for all indications (e.g., H-WAVE Muscle Stimulator) (E1399)** **Microcurrent electrical nerve stimulation (MENS) devices are considered investigational for the treatment of chronic pain and all other indications (e.g., Algonix, Alpha Stim M, MENS 2000-D, MICROCURRENT, Myopulse, Electro-Myopulse 75L, Micro Plus Electrical Nerve Stimulator) (E1399)** **Multimodal devices that incorporate interferential current stimulation, neuromuscular electrical stimulation, and transcutaneous electrical nerve stimulation are considered investigational for all indications (e.g., NexWave) (E0745)** **Neuromuscular electrical stimulators (NMES) are considered investigational when used for ANY of the following unproven indications:** • General muscle strengthening in healthy individuals • Cardiac conditioning • Treatment of denervated muscles • Treatment of idiopathic scoliosis **Pulsed electrical stimulation and pulsed electromagnetic therapy are considered investigational for any indication including, but not limited to neuropathic pain (e.g., diabetic**

Service	Investigational
	peripheral neuropathy), chronic or acute pain, or to treat wounds (including pressure and venous ulcers) (E0761) **Sympathetic electrical stimulation therapy devices are considered investigational for the treatment of chronic pain and for all other indications (e.g., Dynatron STS, Dynatron STS RX) (E1399)** **External trigeminal nerve stimulation (eTNS) for the management of attention deficit hyperactivity disorder is considered investigational (e.g., Monarch eTNS System) (E0733, A4541)** **Transcutaneous electrical modulation pain reprocessing (TEMPR) (also called Scrambler therapy or Calmare pain therapy) is considered investigational for the treatment of cancer pain, chronic pain, neuropathic pain and all other indications (0278T)** **Transcutaneous electrical nerve stimulation of the wrist for treatment of essential tremor is considered investigational (e.g., Cala Trio) (E0734, A4542)** **Transcutaneous supraorbital electrical nerve stimulator is considered investigational for the prevention and treatment of migraine headaches and all other indications (e.g., Cefaly, Allive, Relivion, Heada Term (E1399)** **Transcutaneous tibial nerve stimulation is considered investigational for the treatment of overactive bladder (OAB), including urinary incontinence, frequency, and urgency, and nocturia (e.g., Vivally System, Zida Control Sock), (A4545, E0736, E0737).**

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include the following:

- For neuromuscular electrical stimulator (NMES):
  - Clinical documentation showing that member has disuse atrophy (loss/decrease of muscle mass due to lack of use) where the nerve supply to the muscle is intact and the member has any of the following non-neurological reasons for disuse atrophy:
    - Previous casting or splinting of a limb
    - Contractures due to burn scarring or recent hip replacement surgery (up until the time physical therapy begins)
    - Previous major knee surgery when there is a failure to respond to physical therapy
- For a conductive garment clinical documentation of all of the above plus documentation of one of the following medical reasons:
  - The treatment site is large and using a large number of standard electrodes is impractical
  - There are multiple large treatment sites on the body that make using standard electrodes impractical
  - The treatment site is hard to reach using standard electrodes and lead wires
  - The individual has a skin sensitivity that precludes use of standard electrodes, adhesive tape, or lead wires

Coding

Code	Description
CPT	
64999	Unlisted procedure, nervous system
0278T	Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy), each treatment session (includes placement of electrodes)
HCPCS	
A4541	Monthly supplies for use of device coded at E0733 (new code effective 1/1/2024)
A4542	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist (Cala Trio) (new code effective 1/1/2024)
A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month (used to report Vivally System) (new code effective 10/01/2024)

Code	Description
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve (Monarch eTNS) (new code effective 1/1/2024)
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist Cala Trio) (new code effective 1/1/2024)
E0736	Transcutaneous tibial nerve stimulator (used to report Zida Control Sock) (new code effective 10/01/2024)
E0737	Transcutaneous tibial nerve stimulator, controlled by phone application (used to report Vivally System) (new code effective 10/01/2024)
E0745	Neuromuscular stimulator, electronic shock unit
E0761	Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E1399	Durable medical equipment, miscellaneous
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve (Monarch eTNS) (code termed 1/1/2024)
K1017	Monthly supplies for use of device coded at K1016 (code termed 1/1/2024)
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist) (code termed 1/1/2024)
K1019	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist (code termed 1/1/2024)
L8679	Implantable neurostimulator, pulse generator, any type

Related Information

Definition of Terms

Conductive garment: A form-fitted garment with integrated conductive fibers that are separated from the individual's skin by a layer of fabric.

Disuse atrophy: Gradual wasting or deterioration of a muscle when not used or subjected to prolonged inactivity, such as when an arm is in a cast for a long time (see muscle atrophy).

Muscle atrophy: Muscle wasting or tissue loss that occurs when a muscle is no longer as active as usual. When muscles are no longer used movement and strength decline causing weakness.

Neurogenic atrophy: This most severe type of muscle atrophy occurs when a nerve that connects to the muscle is injured or has a disease. This type of muscle atrophy tends to occur suddenly when compared to disuse atrophy that is more gradual.

Overactive bladder: Bladder storage symptoms with or without urge urinary incontinence, usually with frequency and nocturia as defined by the International Urogynecological Association.[36]

Evidence Review

Description

Electrical stimulation devices are being investigated to improve functional status and relieve pain that is unresponsive to other standard therapies. Electrical stimulation is provided using various devices that noninvasively deliver some form of electrical stimulation to the target site of pain. Various types of electrical stimulation for the treatment of multiple conditions are discussed below.

Background

Galvanic Stimulation Devices

Galvanic stimulation is characterized by high voltage, pulsed stimulation and is used primarily for local edema reduction through muscle pumping and polarity effect. Edema is comprised of negatively charged plasma proteins, which leak into the interstitial space. The theory of galvanic stimulation is that by placing a negative electrode over the edematous site and a positive electrode at a distant site, the monophasic high voltage stimulus applies an electrical potential which disperses the negatively charged proteins away from the edematous site, thereby helping to reduce edema.

H-wave Electrical Stimulation

H-wave stimulation is a distinct form of electrical stimulation, and an H-wave device is US Food and Drug Administration (FDA) cleared for medical purposes that involve repeated muscle contractions. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, H-wave devices are also available for home use. H-wave stimulation has been used for the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. H-wave stimulation has also been used to accelerate healing of wounds such as diabetic ulcers and to improve range of motion and function after orthopedic surgery.

A variety of devices may be used for H-wave stimulation. In general, the FDA has classified them as "powered muscle stimulators." As a class, the FDA describes these devices as "an electronically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area." The H-WAVE Muscle Stimulator (Electronic Waveform Laboratory, Inc., CA) is FDA 510(k) cleared as a class II device.

Microcurrent Stimulation Devices (MENS)

MENS is characterized by subsensory current that acts on the body's naturally occurring electrical impulses in an effort to decrease pain and facilitate the healing process. MENS differs from TENS in that it uses a significantly reduced level of electrical stimulation. TENS blocks pain, while MENS acts on the naturally occurring electrical impulses to decrease pain by stimulating the healing process.

Multimodal Devices

NexWave (Zynex Medical) is a multimodal device that incorporates interferential current stimulation, neuromuscular electrical stimulation, and transcutaneous electrical nerve stimulation. It is compromised of a control device and electrodes for in home use. Per the FDA it is indicated for use for symptomatic relief of chronic intractable pain, muscle re-education, increasing blood circulation, and relaxation of muscle spasms. Use of it for transcutaneous tibial nerve stimulation for the treatment of overactive bladder or urge incontinence is considered off-label use.

Neuromuscular Electrical Stimulation Devices (NMES)

These devices, through multiple channels, attempt to stimulate motor nerves and alternately cause contraction and relaxation of muscles, unlike a TENS device which is intended to alter the perception of pain. NMES are used to prevent or retard disuse atrophy, relax muscle spasm, increase blood circulation, maintain or increase range of motion, and re-educate muscles.

This policy addresses the use of open loop neuromuscular systems which are used for simple tasks such as muscle strengthening alone, and typically in healthy individuals with intact neural control.

Functional neuromuscular stimulators are closed loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters which are required for complex activities such as walking. (These are addressed in a separate policy, see **Related Medical Policies**.)

The RS 4m and RS 2m muscle stimulator are examples of devices that deliver neuromuscular electric stimulation.

Pulsed Electrical and Electromagnetic Stimulation Devices

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and to relieve neuropathic pain and the treatment of wounds that are unresponsive to other standard therapies. Noninvasive electrical stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. Electrical stimulation is provided by an electronic device that noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin. Combined magnetic fields deliver a time-varying magnetic field by superimposing that field onto an additional static magnetic field.

It is proposed that the device treats the underlying cause of the disease by stimulating the injured tissue and improving the overall health of the tissue providing a slow-acting, but longer-lasting improvement in symptoms.

Sympathetic Stimulation Devices

Sympathetic therapy describes a type of electrical stimulation of the peripheral nerves that is designed to stimulate the sympathetic nervous system in an effort to "normalize" the autonomic nervous system and alleviate chronic pain. Unlike TENS or interferential electrical stimulation, sympathetic therapy is not designed to treat local pain, but is designed to induce a systemic effect on sympathetically induced pain.

Sympathetic therapy uses four intersecting channels of various frequencies with bilateral electrode placement on the feet, legs, arms, and hands based on the location of the individual's pain and treatment protocols supplied by the manufacturer. Electrical current is then induced with beat frequencies between 0 and 1000Hz. Treatment may include daily one-hour treatments in the physician's office, followed by home treatments, if the initial treatment is effective.

Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) (CPT 0278T)

Scrambler Therapy/Calmare device is also known as transcutaneous electrical modulation pain reprocessing (TEMPR). It is an electrocutaneous nerve stimulation device. It uses a biophysical rather than a biochemical approach. It is proposed that a "no-pain" message is transmitted to the nerve via disposable surface electrodes applied to the skin in the region of the individual's pain. The perception of pain is then cancelled when the no-pain message replaces that of pain, by using the same pathway through the surface electrodes in a non-invasive way. Regardless of pain intensity, an individual's pain can reportedly be completely removed for immediate relief. Maximum benefit is achieved through follow-up treatments. The individual may be able to go for extended periods of time between subsequent treatments while experiencing significant pain control and relief. The period of time between treatments depends on the underlying cause and severity of the pain in addition to other factors. Treatment utilizing the Calmare medical device may only be done under the direct supervision of allopathic physicians and other qualified licensed healthcare professionals who are certified in its use and application and are familiar with the principles, clinical applications, side effects and hazards associated with transdermal pain modulation.

Transcutaneous Electrical Nerve Stimulation of the Wrist for Treatment of Essential Tremor (Cala Trio)

Cala Trio (Cala Health, Inc) is described as an external upper limb tremor stimulator (also known as a transcutaneous afferent pattern stimulator). The device is a wrist-worn device much like a smartwatch and administers electrical stimulation (neuromodulation) to the median and radial nerves in the affected wrist which is believed to disrupt the neural network relayed through the nervous system to the brain so that tremors in the treated hand are temporarily reduced. The Cala Trio consists of three components: a rechargeable stimulator (where calibration and stimulation amplitude adjustments can be made and full color display messages and instructions are delivered), the wrist band which includes integrated electrodes, and a base station that charges the device. It is available for adults by prescription only for the left hand or right hand in small, medium, or large wrist sizes. It is recommended to wear the device for approximately 40 minutes prior to attempting tasks in which the tremor interferes. The band life, including electrodes is noted to be approximately 90 days.

Transcutaneous Electrical Nerve Stimulator for the Treatment and Prevention of Migraines

Cefaly (STX-Med, Belgium) is a transcutaneous supraorbital nerve stimulator. The device is battery-powered and worn liked a headband whereby self-adhesive electrodes are placed on the forehead covering the supratrochlear and supraorbital nerves (branches of the trigeminal nerve). The device is worn for 20 minutes daily. The device reportedly has a neuromodulatory effect on the treated nerves, thereby blocking pain signals. In 2014, the Cefaly (Cefaly-Technology, Belgium) device received an FDA de novo premarket review pathway with an approved indication for the prophylactic treatment of episodic migraine in individuals 18 years of age or older. It was then cleared for marketing in 2016 through the 510(k) process (K122566). In 2017, the Cefaly Acute and Cefaly Dual were FDA cleared as 510(k) Class II transcutaneous electrical nerve stimulator (TENS) to treat headaches. The Cefaly Acute is indicated for the acute treatment of migraine in individuals with or without aura. The Cefaly Dual is indicated for the acute treatment of migraine with or without aura as well as the prophylactic treatment of episodic migraine.

Figure 1: Cefaly Acute Device

Source: https://www.cefaly.com Accessed January 11, 2024.

Transcutaneous Tibial Nerve Stimulation for Overactive Bladder

Transcutaneous tibial nerve stimulation (TTNS) is being investigated as a non-invasive alternative to percutaneous tibial nerve stimulation, which requires a trained, healthcare professional with specialized equipment to administer a needle close to the tibial nerve and also requires ongoing maintenance of the treatment. TTNS involves placement of electrodes on the surface of the skin for self-administering treatment to stimulate the tibial nerve. The tibial nerve is connected to the sacral plexus, containing L4-S3 nerve fibers which originate from the same spinal area of the parasympathetic nervous system as the bladder (L5-S3). It is hypothesized that by stimulating these nerves, overactive and abnormal bladder nerve signals can be disrupted, thus reducing overactive bladder symptoms, which may include urinary incontinence, urinary urgency, urinary frequency, and nocturia.

One such type of TTNS is the Vivally System, which is controlled by a phone app and is a wearable neuromodulation device that is worn over the ankle. It consists of 2 embedded stimulation electrodes and 3 electromyographical (EMG) sensor electrodes, reuseable gel cushions, and a rechargeable controller (Stimulator). The device is available by prescription only for use in the home after the physician sets the range of stimulation that can be used. Treatment

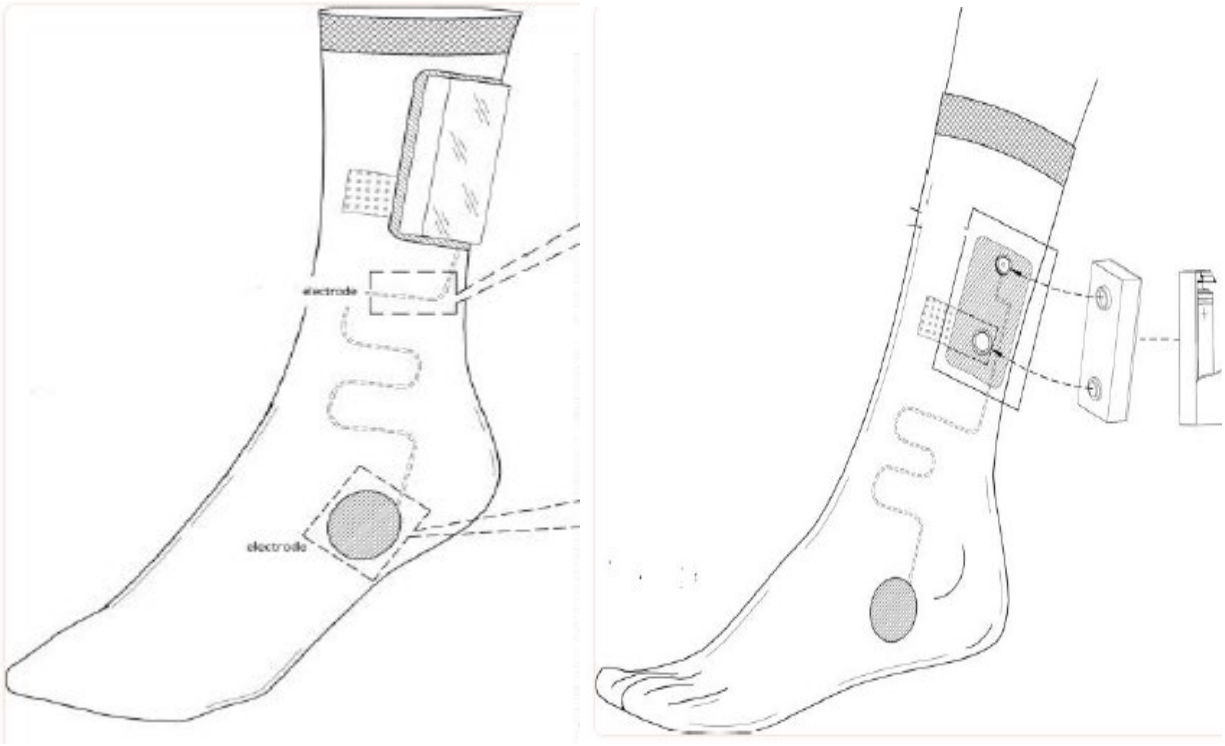
sessions are for 30 minutes one to three times a week. A proprietary algorithm enables the device to adjust stimulation levels as it monitors the EMG response during a treatment session. The mobile app besides enabling the start and management of a treatment session, also contains support tools such as a bladder diary to record symptoms (voids, urgency, urgency leaks, disturbed sleep), fluid intake, and other known dietary agents that impact bladder symptoms such as caffeine, alcohol, and carbonated drinks. The Vivally Cloud Database then collects therapy data, compliance, and symptom tracking over time which can be used by the physician to monitor and manage treatment.

Figure 2: Vivally Neuromodulation System

Source: **https://avation.com/** Accessed September 30, 2024.

Similarly, the Zida Control Sock, is another wearable neuromodulation device that is a wearable sock that comes in four sizes with embedded electronics, reusable electrodes, and a detachable control unit (stimulator) which magnetically snaps onto the embedded sock electrode. The control unit turns the device on/off and allows for an increase or decrease of the intensity of the provided stimulation. It is a home use system that delivers transcutaneous electrical stimulation to the posterior tibial nerve for treatment of symptoms of urinary incontinence, urgency and frequency associated with an overactive bladder. The device is a stand-alone unit and does not require connection with a smartphone. The device is to be used once per week for 30 minutes for a total of twelve weeks. It is available by prescription only.

Figure 3: Zida Control Sock



Source: Cava R, Orlin Y. Home-based transcutaneous tibial nerve stimulation for overactive bladder syndrome: a randomized, controlled study. Int Urol Nephrol. 2022;54(8):1825-1835. PMID: 35622269. Accessed 10/9/2024.

Trigeminal Nerve Stimulator (eTNS) (Monarch)

The Monarch external trigeminal nerve stimulation (eTNS) system is a non-invasive nerve stimulation device indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children aged 7 to 12 years who are not currently taking prescription ADHD medications. Monarch external Trigeminal Nerve Stimulation (eTNS) System is based on a purported mechanism of action that the trigeminal nerve stimulates brain areas thought to be involved in ADHD. While the exact mechanism of action is not yet known, neuroimaging studies have shown that eTNS increases activity in the brain regions that are known to be important in regulating attention, emotion, and behavior. The system consists of a rechargeable, battery-operated external pulse generator which is connected to a single-use, self-adhesive conductive patch that is applied to the forehead just above the eyebrow. When the device is activated, bilateral high-frequency nerve stimulation is delivered to the V1 branch of the trigeminal nerve. The V1 branch of the trigeminal nerve carries sensory nerves from the skin of the forehead to the brain. The level of stimulation delivered by the external pulse generator can be adjusted by the caregiver.

The device is designed to be used in the home at night while the child is sleeping under the supervision of a caregiver, The most common side effects of eTNS use includes drowsiness or trouble sleeping, increase in appetite, teeth clenching, headache, and fatigue. It may take up to 4 weeks for a response to eTNS to become noticeable.

Summary of Evidence

Galvanic Stimulation

A 2009 Cochrane review of electrotherapy concluded that the evidence was of low quality and more studies are needed to reliably establish effectiveness.

H-wave Electrical Stimulation

Two small-controlled trials are insufficient to permit conclusions about the effectiveness of H-wave electrical stimulation as a pain treatment. Additional sham-controlled studies are needed from other investigators, preferably studies that are clearly blinded, specify the handling of any withdrawals, and provide long-term, comparative follow-up data. One small RCT represents insufficient evidence on the effectiveness of H-wave simulation for improving strength and function after rotator cuff surgery. No comparative studies have been published evaluating H-wave stimulation to accelerate wound healing. In addition, no studies were identified that evaluated H-wave stimulation for any clinical application other than those described above. Thus, H-wave electrical stimulation is considered investigational.

Microcurrent Stimulation

Bertolucci and Grey (1995) compared the efficacy of MENS therapy to mid-laser and laser placebo treatment of 48 individuals with TMJ pain. There was a difference in pain and functional outcomes between laser and MENS therapy with laser being slightly higher; however, the difference was not statistically significant. There was no data to suggest whether the effect was durable and whether the effects continued with repeated use.

There is a lack of large controlled clinical trials testing the clinical effectiveness of microcurrent electrical nerve stimulation against placebo devices. Therefore, this treatment remains investigational.

Multimodal Devices

Multimodal devices that incorporate interferential current stimulation, neuromuscular electrical stimulation, and transcutaneous electrical nerve stimulation are unproven as there is no published peer reviewed literature to evaluate the evidence related to this type of device including the off-label use of the NexWave device for the treatment of overactive bladder and urge incontinence as a transcutaneous tibial nerve stimulator.

Neuromuscular Electrical Stimulation (NMES)

Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins).

Pulsed Electrical Stimulation and Electromagnetic Stimulation

PEMF has been used for the treatment of numerous conditions, such as subacromial impingement syndrome, lateral epicondylitis, tinnitus, soft tissue injuries, multiple sclerosis, fibromyalgia, diabetic peripheral neuropathy, plantar fasciitis and for various other conditions related to pain. However, study results are mixed. Some authors report no difference in pain among study groups while others report improvement in various pain parameters after PEMF therapy. In some studies, other treatment modalities were used, making study interpretations and comparisons difficult.

Evidence based guidelines published by the Academy of Neurology (Bril, et al., 2011) do not support electromagnetic field therapy as a treatment for peripheral diabetic neuropathy. The authors noted electromagnetic field treatment is probably not effective for the treatment of peripheral neuropathy.

Studies in the published medical literature comparing electromagnetic therapy devices with established wound care management are lacking. The studies are limited in sample size with poorly defined individual selection criteria and have limited reporting of methodological details. There is little consensus among authors regarding duration of treatment or technique of

application. The results of two Cochrane reviews report no evidence of benefit to electromagnetic therapy when used for wound healing. An additional systematic review also found minimal data to support electromagnetic therapy for the treatment of pressure ulcers.

Sympathetic Therapy

In 2002 Guido and colleagues studied 20 individuals with chronic pain and peripheral neuropathies treated daily with Dynatron STS for 28 days. Pain was reported as moderate to severe by 11 of 15 individuals prior to treatment, with a decrease in pain reported by 6 of the individuals at conclusion of the treatment. The author did not report on the reason why 5 of the 20 individuals did not provide self-reports of pain severity. For the 15 individuals who remained in the study, the authors reported the mean cumulative VAS scores for multiple locations of pain decreased from 107.8 to 45.3. However, drawing conclusions concerning the efficacy of Dynatron STS for the management of chronic, intractable pain is limited due to the small participant population, lack of a randomized control group, placebo effects, and lack of data on pain severity in a quarter of the subjects. There is a lack of peer-reviewed literature concerning the efficacy of sympathetic therapy in terms of pain relief or for any other indication.

Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR)

In 2012, Ricci and colleagues reported on a small retrospective study of 73 individuals whose pain management had been unsatisfactory with other treatments. The primary objective of the study was to assess efficacy and tolerability of the MC5-A Calmare device. This device is described as "scrambling pain information with 'no pain' information in order to reduce the perception of pain intensity." There was no comparator treatment. The individuals were followed for 4 weeks. The authors reported that the pain score had decreased by 74% after 10 days of treatment. The authors concluded that cutaneous electrostimulation with the MC5-A Calmare device can be proposed as part of a multimodality approach to the treatment of chronic pain. However, they cautioned that further studies on larger numbers of individuals are needed to assess its efficacy, to quantify the effects of inter-operator variability, and to compare results obtained from the active device versus those from a sham machine.

In 2015, Moon and colleagues reported on a multicenter analysis which sought to identify which factors are associated with treatment outcomes for Calmare therapy. They gathered data from 3 medical centers on 147 individuals with various pain conditions who underwent a minimum of either 3 Calmare therapies on consecutive days or 5 therapies overall. A successful outcome was

predefined as ≥50% pain relief on a 0 to 10 numerical rating scale that persisted for longer than 1 month after the last treatment. Overall, the success rate was 38.1%. Variables found to be associated with a positive outcome included the presence of neuropathic or mixed pain, and treatment at either Walter Reed or Seoul National University. Factors that correlated with treatment failure were disease or traumatic/surgical etiologies and antidepressant use. They concluded that a neuropathic or mixed neuropathic-nociceptive pain condition was associated with a positive treatment outcome and suggested that investigators consider these findings when developing selection criteria in clinical trials designed to determine the efficacy of Calmare therapy.

Transcutaneous Electrical Nerve Stimulation of the Wrist for Treatment of Essential Tremor

For individuals who have essential tremor who receive TENS (Cala Trio), the evidence includes a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results from the nonrandomized study suggest that TENS therapy is effective and safe for individuals with essential tremor. However, the trial was limited by its open-label, single-arm design, lack of defined standards for what constitutes a clinically meaningful improvement in stated endpoints, and exclusion of individuals who exited the study early from the pre-specified primary and secondary endpoint analyses. Further studies comparing TENS to standard of care therapy for essential tremor are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transcutaneous Electrical Nerve Stimulator for the treatment and prevention of migraines

For individuals who have chronic or episodic migraine who receive TENS for treatment of acute migraine, the evidence includes 3 double-blind, sham-controlled RCTs. Two of the RCTs evaluated healthcare-provider administration of a TENS device during a single episode in emergency departments, and 1 evaluated self-administration of the device at home during acute episodes over a 3-month period. The studies conducted in emergency departments showed clinically and statistically significant reductions in pain intensity and medication use within 2 hours of use. The self-administration study had mixed results: The difference in median pain scores before and after treatment was significantly higher in the TENS group at months 1 and 2, but at month 3 the difference was not statistically significant. Function and analgesic

medication use did not differ between groups at any time point. Strengths of the RCTs included the use of a sham device and blinded outcome assessment using validated outcome measures. Although short-term pain relief was demonstrated at some time points, the quality of the overall body of evidence was downgraded due to inconsistency of results and heterogeneity in study settings. It is not clear whether the pain intensity reductions demonstrated in emergency department settings would generalize to other settings over longer time periods. Supporting evidence from RCTs is needed. Additionally, based on the existing evidence, it is unclear how TENS would fit into the current migraine treatment pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The specific intended use must be specified in order to adequately evaluate net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic or episodic migraine who receive TENS for migraine prevention, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. The RCT (N=67) reported a greater proportion of participants achieving at least a 50% reduction in migraines with TENS than with sham placebo and modest reductions in the number of total headache and migraine days. In the intention-to-treat analysis, the reduction in the number of migraine days (run-in vs. 3-months) was not statistically significant. The proportion of responders (≥50% reduction in the number of migraine days/month) significantly higher in the TENS group. The number of migraine attacks from the run-in period to the 3-month evaluation, number of headache days, and antimigraine medication use were significantly lower for the active TENS group. The severity of migraine days did not differ significantly between groups. This manufacturer-sponsored trial needs corroboration before conclusions can be made with certainty about the efficacy of TENS for preventing migraine headaches. Additionally, based on the existing evidence, it is unclear how TENS would fit into the current migraine prevention pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transcutaneous Tibial Nerve Stimulation for Overactive Bladder

For individuals who have overactive bladder who receive transcutaneous tibial nerve stimulation using the Vivally System, the evidence includes one multicenter, open-label, single arm study,

(N=96). Participants were measured via questionnaires related to changes in bladder symptoms and quality of life metrics at 1, 4, 8, and 12 weeks. The mean age was 60.8 and 88.5% were female The results demonstrated reductions in 3-day bladder diary parameters (daily voids, incontinence, and urgency) at 12 weeks with mean urinary frequency events reduced to 2.8 events from baseline and mean urinary urge incontinence reduced to 1.91 events, which remained at 12 months, along with reported improvements in quality of life. All participants had symptoms of OAB ≥ 3 months, with a minimum average of 10 voids/day, had a detectable EMG signal with the system, had to tolerate a 30 minute treatment session, and had to remain drug naïve or stable on a OAB medication regimen. At the end of 12 weeks a total of 50 participants signed a new informed consent and continued keeping bladder diaries and tapered therapy from 1-3 sessions per week to two 30-minute sessions per month. Data was then analyzed at 6 months (N=47) and 12 months (N=39).The authors note that (N=29) had discontinued treatment during the initial 12 weeks. Limitations of the study include small sample size, as there was a large loss of participants at the longer 12-month follow-up analysis. There was no comparator and no break out of the participants in how many were treatment naïve and how many were actually on a stable OAB medication regimen and the difference in results between the two. The results can not be generalized to the male population since the majority of participants were female. The study was industry sponsored. The evidence also includes one randomized multicenter, prospective, double-blind, sham-controlled trial where participants were randomized 1:1 to either active therapy with the Vivally System or sham therapy (N=125) through 12 weeks of follow-up in which they were instructed to use the system for 30 minute sessions, three times weekly. The mean age was 62.7 and the majority of particpants were female (96.8%). Inclusion requirements: symptoms of OAB for ≥ three months, average daily voids ≥ 11, or one daily leak on a 3 day bladder diary. Participants also had to have a detectable EMG signal. Participants could continue on a stable OAB regimen if done through out the study. The sham group participants utilized all components of the system, including use of the mobile application, which simulated graphical representation of the stimulation parameters, but they received no actual stimulation. Participants were evaluated remotely or in the office after 3, 8 and 12 weeks. All outcome measures were reported electronically through the mobile application. The primary efficacy endpoint was defined as ≥ 50% reduction in daily urgency leaks or a ≥ 30% reduction in daily voids from baseline. A total of 111/125 (88.8%) of randomized particpants completed follow-up. The results demonstrated that a modified Intent-to-Treat population (n=107) was used for efficacy analyses: in the Vivally group (n= 55), the response rate was higher (83.6%) compared to the sharm group (n=52) (57.7%; p=0.032). The authors noted a favorable safety profile with no serious adverse events. The participant satisfaction with the device was high 90/92 (97.8%) and therapy compliance was above 92% for both the Vivally and sham groups. However, there was not a significant difference between the two groups in analysis of improvement by specific symptom such as mean differences in 24-

hour voids (3.7 for active and 3.4 for sham) and urgency leaks (2.6 for active and 3.1 for sham). Limitations of the study include small sample size and longer term follow-up is needed to determine the sustainability of the treatment response. The results can not be generalized to the male population since the majority of participants were female The study was industry sponsored.

For individuals who have overactive bladder who receive transcutaneous tibial nerve stimulation using the Zida Control Sock wearable neuromodulation system, the evidence includes a prospective randomized, blinded, sham-controlled trial, (n=40). Participants were randomized to two groups in a 1:1 ratio: the treatment group: using the Zida device (n=21, mean age 64) and the sham control group (n=19, mean age 72). 80% of the participants were female and 20% were male. Inclusion criteria included a score on the male or female International Consultation on Incontinence Questionaire Lower Urinary Tract Symptoms Module of ≥ 60, Participants that were on an OAB medication regimen underwent a two-week washout period in which the medications were discontinued. Exclusion criteria included botulinum toxin intravesical injection within 36-months of enrollment, or treatment within the previous year with another form of neuromodulation for OAB. The participants were fitted with the sock via face-to-face instruction on how to use the device. Both groups self-administered the treatment for 30 minutes, once weekly, for a duration of 12 weeks. The sham-control group received a sham device that looked identical to the Zida device. A green operating light turned on and automatically shut off after 30 minutes, however no electrical stimulation was delivered. Participants were in telephone contact weekly with a study coordinator to verify compliance. Participants completed at baseline and at 12 weeks two 3 day bladder diaries (6 days) and a quality of life survey. The primary endpoint was a 50% reduction in urgency voids with or without incontinence or at least a 30% reduction in their 24 hour frequency. The results demonstrated a success rate of 80% in the Zida group versus 39% in the sham control group for urgency voids (p=0.02), 25% in the Zida group versus 0% in the sham control group had at least a 30% reduction in 24-hour frequency (p=0.048), and 75% in the Zida group versus 33% in the sham control group for incontinence success. All participants had 100% compliance with weekly treatments, however, 2 particpants, one from each group, were not included in the final analysis. Limitations of the study included very small sample size, longer term follow-up is needed to determine the sustainability of the treatment response, The results can not be generalized to the male population since the majority of participants were female . The authors acknowledge that electrode placement in the various sizes of the socks might be less than optimal than an electrode placed by professionally trained personnel. The study was industry sponsored.

Trigeminal Nerve Stimulation (Monarch eTNS System)

For individuals who have attention deficit hyperactivity disorder (ADHD) who receive TENS, the evidence includes one RCT. McCough et al (2019) assessed the efficacy and safety of TENS in a double-blind, sham-controlled pilot study of pediatric individuals with ADHD. 62 individuals (8 to 12 years) with ADHD based on the KSADS and clinical interview with a minimum total of 24 on the clinician-administered parent ADHD-IV Rating Scale, baseline CGI-S ≥4, and full-scale IQ ≥85. Children were medication free for at least 1 month prior to enrollment. TENS device (Monarch eTNS System) administered nightly for 4 weeks (n=32). Sham TENS device administered nightly for 4 weeks (n=30). The study was a 4-week trial followed by 1 blinded week without intervention. Clinical assessments included weekly clinician-administered ADHD-Rating and Clinical Global Impression (CGI) scales, and quantitative electroencephalography (EEG) at baseline and week 4. 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 individual 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 individuals with ADHD. Limitations cited were sample size and short duration of treatment and follow-up. Further studies comparing TENS to standard of care therapy for ADHD are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that may influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04428619	Percutaneous Electrical Field Stimulation for Adults with Irritable Bowel Syndrome	54	Nov 2024 (recruiting)
Unpublished			
NCT04239976	Scrambler therapy for the reduction of chemotherapy-induced neuropathic pain	16	Mar 2022
NCT05480215	Prospective Study for Symptomatic Relief of Action Tremor with Cala Trio Using Trio+ Bands	20	Dec 2021

NCT: national clinical trial.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Pediatrics (AAP)

In 2019 the AAP updated its clinical practice guideline for the diagnosis, evaluation, and treatment of ADHD in children and adolescents[56]. The revised guideline states that external trigeminal nerve stimulation (eTNS) cannot be recommended as a treatment for ADHD because supporting evidence is "sparse and in no way approaches the robust strength of evidence documented for established medication and behavioral treatments for ADHD; therefore it cannot be recommended as a treatment of ADHD without considerably more extensive study on its efficacy and safety."

The American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

In 2024 the AUA/SUFU stated that "clinicians may offer select non-invasive therapies to all patients with OAB", one of which they note is transcutaneous tibial nerve stimulation. They also note "while safety profiles are excellent across modalities, with few adverse effects and a high

risk-benefit ratio, all non-invasive therapies do not have equivalent efficacy and the evidence base is highly variable."

International Essential Tremor Foundation

In 2021, IETF recommended Cala Trio and/or other non-invasive devices as an add-on non-pharmacological/non-surgical treatment option that could be used to reduce tremor in a targeted arm after first -line pharmacological approaches have been trialed, or after second-line and third-line pharmacological approaches have been trialed. This was based on expert opinion without a formal review process and did not include strength of evidence ratings, nor was there any description of management of conflict of interest.

National Institute for Health and Care Excellence (NICE)

In 2022, the NICE published updated guidance on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine in adults. The recommendation stated, "the evidence for treating an acute migraine attack is adequate but, for treating subsequent attacks , is limited in quality and quantity. They recommend special arrangements for clinical governance for treating acute migraine. . The evidence for preventing migraine is inadequate in quality and should only be used in the context of research.."[78]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

- In 1992, the H-Wave muscle stimulator (Electronic Waveform Lab, Huntington Beach, CA) was cleared for marketing by FDA through the 510(k) process. FDA classified H-wave stimulation devices as "powered muscle stimulators." As a class, FDA describes these devices as being "intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area."
- Calmare Pain Therapy Medical Device also known as the Scrambler Therapy MC-FA TENS device was FDA 510(k)- cleared in 2009 (K081255) and classified as a multi-channel transcutaneous electrical nerve stimulator (TENS). European CE mark-certified for the

treatment of oncologic and neuropathic pain through biophysical stimulation. The Device has five separate channels, convenient dial selectors with five corresponding channel meters, indicator lights and an LCD display to monitor operation. FDA Product Code: GZJ.

- In 2011 the NexWave combination neuromuscular electrical stimulator, interferential stimulator, and transcutaneous electrical nerve stimulator was cleared for marketing by the FDA through the 510(k) process (K111279) as it was determined to be substantially equivalent to predicate devices. The indications for use were noted for the interferential mode for the symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain. The neuromuscular electrical stimulation mode for muscle re-education, prevention of disuse atrophy, increasing local blood circulation, maintaining range of motion, and relaxation of muscle spasms, the transcutaneous electrical stimulation mode for management and symptomatic relief of chronic intractable pain, post-traumatic pain and post-surgical pain. FDA Product Code: IPF, GZJ, LIH

- In 2014, the Cefaly (STX-Med), which is a TENS device, was granted a de novo 510(k) classification by the FDA for the prophylactic treatment of migraine in patients 18 years of age or older.1, The Cefaly Acute and Cefaly Dual devices were cleared by the FDA through the 510(k) process for the acute treatment of migraine in patients in 18 years of age or older and for both the acute treatment and prophylaxis of migraines in adults, respectively, in 2017. Other TENS devices cleared by the FDA through the 510(k) process for the prophylactic treatment of migraine in patients include Allive (Nu Eyne Co), Relivion (Leurolief Ltd.) and HeadaTerm (EEspress) among others.[47],FDA product code: PCC.

- In 2017, the FDA reviewed the Cala ONE TENS device (Cala Health) via the de novo pathway (DEN170028) and granted approval for the device as an aid in the transient relief of hand tremors following stimulation in the affected hand of adults with essential tremor. This prescription device is contraindicated for use in individuals with an implanted electrical medical device, those that have suspected or diagnosed epilepsy or other seizure disorder, those who are pregnant, and individuals with swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions. In 2018, the Cala ONE device was cleared for marketing by the FDA through the 510(k) process (K182706) as substantially equivalent to its predicate device. In October 2020, the FDA granted breakthrough device designation to the Cala Trio device for the treatment of action tremors in the hands of adults with Parkinson's disease. In 2021, the Cala Trio was rebranded and received FDA 510(k) clearance (K203288) as substantially equivalent to the predicate device, Cala One. In November 2022, the Cala kIQ device was approved via the 510(k) pathway (K222237). The device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. It was also approved to aid in the temporary relief of postural and kinetic

hand tremor symptoms that impact some activities of daily living in the treated hand of adults with Parkinson's disease. FDA Product Code QBC.

- In 2019, the FDA permitted marketing of the first medical device to treat attention deficit hyperactivity disorder (ADHD) - the Monarch external Trigeminal Nerve Stimulation (eTNS) System by NeuroSigma. The FDA reviewed the system through the de novo premarket review pathway (DEN180041). This prescription only TENS device is indicated for individuals 7 to 12 years of age who are not currently taking prescription ADHD medication. The Monarch eTNS System is intended to be used in the home under the supervision of a caregiver. The device generates a low-level electrical pulse and connects via a wire to a small patch that adheres to a individual's forehead, just above the eyebrow. FDA Product code: QGL.

- In 2021, the Zida "Control Sock" (formally known as Zida Wearable Neuromodulation System) (Exodus Innovations, New York, NY, now Zida LLC) was cleared for marketing by the FDA through the 510(k) process (K192731) as substantially equivalent to a percutaneous tibial nerve stimulation device (Urgent PC Neuromodulation System). It is intended to treat patients with an overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence through nerve stimulation via transcutaneous electrical stimulation of the posterior tibial nerve near the ankle. FDA Product Code: NAM.

- In 2023, the Vivally System (Aviation Medical,Inc., Columbus, OH) was cleared for marketing by the FDA through the 510(k) process (K220454) as it was determined to be substantially eqivalent to predicate devices. The indications for use: "to treat patients with the bladder conditions of urge urinary incontinence and urinary urgency." It is described as a "non-invasive wearable bladder control therapy system utilizing neuromodulation to treat patients with bladder conditions of the urge urinary incontinence and urinary urgenvcy by stimulating the tibial nerve. FDA Product Code: NAM.

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History

Date	Comments
09/10/02	Add to Durable Medical Equipment Section - New Policy. Replaces 1.01.13 H-Wave Electrical Stimulation; 1.01.104 (1.01.09) Transcutaneous Electrical Nerve Stimulator (TENS); 1.04.03 Sympathetic Therapy for the Treatment of Pain; 7.01.29 Percutaneous Electrical Nerve Stimulation (PENS)

Date	Comments
04/15/03	Replace Policy - Policy reviewed with references added.
05/13/03	Replace Policy - Policy section revised for clarification only.
10/16/03	Replace Policy - Interferential Stimulation Devices description updated; references added. No change to policy statement.
01/13/04	Replace Policy - TMJ as investigational for TENS was added. This is consistent with TMJ policy.
06/08/04	Replace Policy - Policy reviewed; No change to policy statement.
07/13/04	Replace Policy - Description of PENS revised; information on percutaneous neuromodulation included; policy statement revised to indicate that percutaneous neuromodulation considered investigational. No change in policy statement regarding PENS.
09/01/04	Replace Policy - Policy renumbered from PR.1.01.107. No date changes.
09/14/04	Replace Policy - Policy statement revised by adding pulsed electrical stimulation with the BioniCare to be considered investigational as a treatment for osteoarthritis. Rationale Section updated.
12/14/04	Replace Policy - Description of TENS revised; information on dementia added; reference added; Medicare policy language on TENS added. No change to policy statement.
02/08/05	Replace Policy - RS-4i Sequential Stimulator information added. No change to policy statement.
05/31/05	Update only to web - HCPCS codes added only—no other changes and not presented to MPC.
09/13/05	Replace Policy - Interferential Stimulation and PENS/ PNT added to Rationale section. References updated; no change to policy statement.
02/06/06	Codes updated - No other changes.
05/26/06	Update Scope and Disclaimer - No other changes.
07/11/06	Replace Policy - Update description to include detail of RS 4M and RS 2M muscle stimulators; no change to policy statement.
04/10/07	Cross Reference Update - No other changes.
06/12/07	Replace Policy - Policy updated with literature review; references added. No changes in policy statement. Reviewed by practicing orthopedic surgeon in May 2007.
05/13/08	Replace Policy - Policy updated with literature search. Policy statement was updated to include cranial electrostimulation therapy is considered investigational for all indications listed. The manufacturer provided many articles to be reviewed. Many of them were from the 1990s and earlier. Most of the later studies were not regarding the FDA approved labeled indications. Additional and much larger double-blinded, sham

Date	Comments
	controlled studies are needed to document long-term effects of CES. References and code added to support the update.
01/13/09	Code Update - Code E0770 added, effective 1/1/09.
08/11/09	Replace Policy - Policy updated with literature search; references added. No change to policy statement.
04/13/10	Cross Reference Update - No other changes.
06/08/10	Replace Policy - Policy updated with literature search, reference added. Added medically necessary statement re: conductive garment and TENS/IF. Also included Flex IT to investigational statement.
06/13/11	Replace Policy - Policy updated with literature search, reference added. No change to policy statement.
01/25/12	HCPCS codes S8130 and S8131 added to policy.
01/26/12	CPT code 0278T added.
03/13/12	Replace policy. Policy revised by removing indications, descriptions, and rationale addressed in separate policies: 1.01.13, 1.01.24, 1.01.27, 7.01.29, and 8.01.58. Policy now addresses TENS, open loop neuromuscular electrical stimulation, galvanic, microcurrent, cranial electrostimulation and sympathetic electrical stimulation devices.
04/17/12	Related Policies updated; 7.01.546 added to replace 7.01.25 which has been deleted.
08/24/12	Update Related Policies. Change title for 7.01.106
11/20/12	Update Related Policies. Add 8.01.58.
02/11/13	Replace policy. Removed information on cranial electrostimulation which is addressed in Medical Policy 8.01.58. Added policy statement on scrambler therapy.
12/30/13	Coding update. HCPCS code E0762 removed; this is addressed in policy No. 1.01.27, Electrical Stimulation for the Treatment of Arthritis. Remove Related Policy 1.01.19; it was archived effective 12/9/13.
03/21/14	Update Related Policies. Delete 7.01.106 and replace with 7.01.553.
05/12/14	Annual Review. TENS policy statements and information removed. Added references 3 and 4.
06/09/14	Interim update. HCPCS codes E0720, E0730 and E0731 are no longer reviewed and from the policy. The Policy section has been updated with removal of the policy statement related to code E0730 and the TENS unit.
03/10/15	Annual Review. Policy updated with literature search through November 2014. Added statement from medical policy 1.01.27 (that is now archived) "Electrical stimulation is considered investigational for the treatment of osteoarthritis or rheumatoid arthritis" along with the HCPCS code. Added policy 7.01.529, removed policy 1.01.27 from Related Policies section. Added information about conductive garment to the Policy Guidelines. Added Definition of Terms to Policy Guidelines. Regulatory Status section

Date	Comments
	updated with additional device names. Reference 6-12, 14 added; others renumbered. Added code E0762. Policy statement added as noted. Coding update: CPT codes 64553-64590 removed as there are more specific codes listed; HCPCS codes S8130, S8131 removed as these are not being utilized; HCPCS codes E0770 and L8680 removed as these are listed on other policies to which they apply.
04/17/15	Update Related Policies. Remove 7.01.553 and 7.01.529 as they were archived, and add 7.01.07.
01/12/16	Annual Review. Policy updated with literature search through November 2015. No studies were found which would prompt a change in the policy statement. References added.
01/29/16	Minor update. Add code L8679 to coding table.
06/01/17	Annual Review, approved May 23, 2017. Put into new format. No changes to policy statement.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018. References 16-23 added. Minor edits to policy statements for clarity. Otherwise, policy statements unchanged. Removed 7.01.07 from Related Policies, added 8.01.58. Removed CPT code 64550.
08/01/18	Interim Review, approved July 10, 2018. Policy updated with literature review through June 2018. References 24-32 added. Policy statement modified to "Pulsed electrical stimulation and pulsed electromagnetic therapy are considered investigational for any indication including, but not limited to the treatment of osteoarthritis, rheumatoid arthritis, neuropathic pain (diabetic peripheral neuropathy), post-operative or non-post-operative pain, or to treat wounds."
06/01/19	Annual Review, approved May 7, 2019. Policy updated with literature review through January 2019; no references added. Minor edits for clarity; otherwise policy statement unchanged. Removed CPT code 97014 and HCPCS code G0283.
06/01/20	Annual Review, approved May 12, 2020. Policy updated with literature review through January 2020; references added. Added H-wave electrical stimulation and transcutaneous supraorbital electrical nerve stimulator are considered investigational Otherwise, policy statements unchanged. HCPCS code E0761 was added.
08/01/20	Update Related Policies. Add 1.01.24 Interferential Current Stimulation.
06/01/21	Annual Review, approved May 11, 2021. Policy updated with literature review through December 13, 2020; references added and some references deleted. Added remote electrical neuromodulation (REN) (e.g., Nerivio Migra) as investigational. Other minor edits made for greater clarity.
10/01/21	Coding update, Added HCPC code K1023.
06/01/22	Annual Review, approved May 10, 2022. Policy updated with literature review through January 18, 2022; references added. Added percutaneous electrical nerve field stimulation (PENFS) used to treat abdominal pain associated with irritable bowel

Date	Comments
	syndrome as investigational (e.g., IB-Stim). Added CPT codes 0720T and 64999. Removed HCPCS code E0762.
08/01/22	Interim Review, approved July 12, 2022. Added trigeminal nerve stimulation for the treatment of ADHD is considered investigational. Removed remote electrical neuromodulation (REN) (e.g., Nerivio) as it is now reviewed in 7.01.171 Remote Electrical Neuromodulation for Migraine. Added HCPCS codes K1016 and K1017. Removed HCPCS code K1023.
10/01/22	Interim Review, approved September 13, 2022. Added transcutaneous electrical nerve stimulation of the wrist for treatment of essential tremor is considered investigational (e.g., Cala Trio). Removed determination statement from HCPC E1399. Changed the wording from "patient" to "individual" throughout the policy for standardization.
05/01/23	Annual Review, approved April 24, 2023. Policy reviewed. References updated. Policy statements unchanged. Updated code description for HCPCS code K1019.
08/01/23	Interim Review, approved July 10, 2023. Removed policy statement for percutaneous electrical nerve field stimulation (PENFS) used to treat abdominal pain associated with irritable bowel syndrome (e.g., IB-Stim) as it is now reviewed in Policy 2.01.106 Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome. Deleted CPT code 0720T due to criteria change.
10/01/23	Interim Review, approved September 12, 2023. Added policy statement that multimodal devices that incorporate interferential current stimulation, neuromuscular electrical stimulation, and transcutaneous electrical nerve stimulation are considered investigational for all indications (e.g., NexWave). References added.
10/04/23	Updated related policy. Policy 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy was renumbered to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy.
11/01/23	Update Related Policy. 7.01.574 – title changed from “Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain” to “Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain and Other Conditions.”
01/01/24	Coding update. Added new HCPCS codes A4541, A4542, E0733 and E0734 and termed codes K1018 & K1019.
03/01/24	Annual Review, approved February 12, 2024. Policy reviewed. References added. Policy statements unchanged. Removed termed HCPCS codes K1016 & K1017.
05/01/24	Minor update to related policies. 8.01.58 was replaced with 8.01.540 Cranial Electrotherapy Stimulation and Auricular Electrostimulation.
09/11/24	Minor update to related policies. 7.01.20 was replaced with 7.01.593 Vagus Nerve Stimulation.
12/01/24	Interim Review, approved November 12, 2024. Added policy statement: “transcutaneous tibial nerve stimulation is considered investigational for the treatment

Date	Comments
	of overactive bladder (OAB)" References added. Added HCPCS codes A4545, E0736 and E0737.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.