MEDICAL POLICY

Excellus

An independent licensee of the Blue Cross Blue Shield Association

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

POLICY STATEMENT

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

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

III. Based upon our criteria and assessment of the peer-reviewed literature, the BioniCare Stimulator Model BIO-1000 has not been proven to facilitate the repair of cartilage in patients with arthritis and, therefore, is considered **investigational** for this indication.

IV. Based upon our criteria and assessment of the peer-reviewed literature, the following stimulation devices have not been proven medically effective and, therefore, are considered **investigational** for all indications:

A. Percutaneous electrical stimulators (PENS)
B. Percutaneous neuromodulation therapy (PNT)
C. Interferential Stimulation (e.g., RS 4i Sequential Stimulator, Empi IF 3Wave)
D. Trigeminal Nerve Stimulators (e.g., Cefaly, Monarch)
E. Remote Electrical Neuromodulation (REN) devices (e.g., Nerivio)
F. External Upper Limb Tremor Stimulator (e.g., Cala One, Cala Trio)
G. Cranial Electrical Stimulation (e.g., Alpha Stim-AID, Carvella, CES Ultra)
H. Peripheral Magnetic Stimulation (e.g., Axon Therapy)

V. 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.

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

Refer to Corporate Medical Policy #1.01.48 Neuromuscular Stimulation.

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

Refer to Corporate Medical Policy #3.01.09 Transcranial Magnetic Stimulation

POLICY GUIDELINES

I. Coverage of durable medical equipment is contract dependent unless required under federal or state mandates. Please contact the Customer Care (Member or Provider) Department to determine benefits available under a member's subscriber contract.

II. Repair and/or replacement of a medically necessary stimulator, accessories, and/or components not under warranty will be considered medically appropriate when the following criteria are met:

A. Physician documentation includes ALL of the following:
1. date of device initiation,
2. manufacturer warranty information, and
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;
AND ONE OF THE FOLLOWING APPLY:

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.

III. 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.

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

DESCRIPTION

I. **Transcutaneous Electrical Nerve Stimulation (TENS)** is the application of an electrical current through the skin to stimulate the nervous system. The electronic device is attached to the surface of the skin over the peripheral nerve to be stimulated and is used to relieve chronic intractable pain, post-operative pain and pain associated with active or post-trauma injury unresponsive to other standard pain therapies. TENS consists of an electrical pulse generator, usually battery operated, that is connected by wire to two or more electrodes, which are applied to the surface of the skin at the site of the pain. Several TENS devices are classified by the U.S. Food and Drug Administration (FDA) (e.g., The BioniCare Stimulator Model BIO-1000, RST Sanexas).

II. **Percutaneous Electrical Nerve Stimulation (PENS)** is a similar concept to TENS but different in that needles are inserted around or adjacent to the nerve serving the painful stimuli and then stimulated. PENS is generally reserved for patients who fail to get pain relief from TENS. Percutaneous neuromodulation therapy (PNT) is a variant of PENS in which the needles are inserted at specific anatomical landmarks on the back.

III. **H-wave stimulation** is a form of electrical stimulation that differs from other forms of stimulation in terms of its waveform. H-wave devices are available for home use as durable medical equipment. H-wave stimulation has been used for pain control, treatment of diabetic neuropathy, muscle sprains, TMJ dysfunctions or reflex sympathetic dystrophy. It has also been used to accelerate healing of wounds (e.g., diabetic ulcers).

IV. **Interferential stimulation** is an anti-inflammatory based treatment modality. The interferential stimulator crosses two medium frequency alternating currents, which penetrate deep into soft tissue. It is used 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.

V. **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 used to treat a wide variety of symptoms especially for acute and chronic pain relief. The TruWave Plus is an example of a combination device.

VI. **TENS for the treatment and prevention of migraines**. The Cefaly device received FDA approval on March 11, 2014 for 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.

VII. **Trigeminal nerve stimulation.** Trigeminal nerve stimulation for treatment of attention deficit hyperactivity disorder (ADHD). The Monarch, an external trigeminal nerve stimulator (eTNS), was approved by the FDA on April 19, 2019. 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.

VIII. **Remote Electrical Neuromodulation (REN).** The Nerivio device was approved by the FDA in May of 2019, and in January of 2021, it was approved for adolescent use. It is a wireless stimulation device applied to the lateral upper arm in 45-minute sessions and triggers weak electrical impulses to start conditioned pain modulation, a proprietary

electrical signal to stimulate noxious sensory fibers and relieve acute migraine. It is controlled by a mobile app that includes a migraine diary to track migraine headaches and treatment sessions. Each device functions for 12 treatments after which, it is disposed and a new device is required.

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

X. **Cranial Electrical Stimulation (CES).** A cranial electrotherapy stimulation (CES) device (e.g., Alpha Stim-AID)is a handheld prescription device that delivers an electronic microcurrent through small clips worn on the earlobes. The current travels through the brain to stimulate specific groups of nerve cells. It is reportedly able to provide significant anxiety relief, mood normalization, pain relief, and better sleep. The user can select the level of stimulation and increase or reduce as needed, typically for 20- minute sessions.

XI. **Peripheral Magnetic Stimulation, Axon Therapy.** A peripheral nerve stimulation device, also known as Axon Therapy (NeuraLace Medical, Inc.) received FDA approval through the Section 501(k) premarket approval process in June, 2021. Axon therapy utilizes a figure-8 shaped coil to deliver focused magnetic pulses to damaged A-Beta sensory nerve fibers during a 13-minute treatment and is intended to simulate peripheral nerves for the relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years and older.

RATIONALE

A number of interferential stimulator devices have received FDA approval including the Medstar 100 (Mednet Services and the RS-4V (RS Medical). In 1997, the FDA approved the BioniCare Stimulator Model BIO-1000 for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee; in 1999 it was approved as adjunct therapy for reducing the level of pain and stiffness associated with osteoarthritis of the hand.

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. Published clinical trials have not provided evidence to support the efficacy of interferential stimulation compared to current treatment options. An abstract of 101 patients presented at the 2004 annual meeting of the American Academy of Orthopedic Surgeons reported that 50% of patients avoided total knee arthroplasty by using the BioniCare system. However, there was no randomly assigned control group in this abstract. The FDA classified this device as a TENS unit, however, the manufacturer has indicated that it is a new category of device, as it uses a different array of proprietary electrical amplitudes than a TENS unit and does not function to stimulate nerves. Instead, the BioniCare device is purported to stimulate chondrogenesis. However, no studies have been performed to evaluate whether chondrogenesis occurs with use of this device.

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

The peer-reviewed literature concerning PENS and PNT consist of small, single center, randomized control trials. The studies do not address long-term improvement of pain and functional outcomes. There is no evidence concerning the adverse effects of PENS and PNT or their acceptability over repeated courses of therapy. Therefore, the available evidence does not permit conclusions about the long-term effectiveness of PENS and PNT.

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

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

Pahwah et al (2018) studied the use of a novel peripheral (radial and median nerves) stimulation device for the treatment of essential tremor via a RCT of 77 patients and compared to sham stimulation. Although the primary endpoint (an improvement in the Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) Archimedes spiral scores) was not met, the authors noted significant improvements in some subject-rated tasks in activities of daily living and clinical global impression-improvement (CGl-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.

CES has been investigated for individuals with headache, chronic pain, depression, and Parkinson disease. Trials that studied headache found only marginal benefits. Trials studied for chronic pain did not show a benefit. The evidence for the use of CES for psychiatric, behavioral, or neurologic conditions include a systematic review and a number of small

sham-controlled RCTs, only one of which (Barclay et al, 2014) found a significant benefit for its use in depression, but the sample size was small with strong potential placebo effects. Additionally studies had significant heterogeneity in study populations and treatment protocols. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Peripheral magnetic stimulation differs from electrical stimulation in that it doesn't 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.

CODES

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

CPT Codes

Code	Description
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve
97014	Application of a modality to one or more areas; electrical stimulation, unattended
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
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 (*effective 1/1/23*)
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) (*effective 1/1/23*)
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 (*effective 1/1/23*)
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) (*effective 1/1/23*)

HCPCS Codes

Code	Description
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
E0720	TENS, two lead, localized stimulation
E0730	TENS, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric).
The following HCPCS code is considered investigational if not used as a TENS device:	
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
The following HCPCS codes are considered investigational:	
K1002	Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
K1017	Monthly supplies for use of device coded at K1016
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist
K1019	Monthly supplies for use of device coded at K1018
K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm **(***~~effective 10/01/21~~***).**
S8130	Interferential current stimulator, 2 channel
S8131	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)
G13.0-G13.1	Paraneoplastic neuromyopathy and neuropathy (code range)
G43.0-G43.919	Migraine (code range)
G44.0-G44.89	Other headache syndromes (code range)

Code	Description
G54.8	Other nerve root and plexus disorders
G55	Nerve root and plexus compressions in diseases classified elsewhere
G56.00-G56.92	Carpal tunnel syndrome and mononeuropathies, upper limb (code range)
G57.00-G57.63	Lesion of sciatic nerve, lower limb (code range)
G57.8-G59	Mononeuropathy (code range)
G63	Polyneuropathy in diseases classified elsewhere
G65.0-G65.2	Sequelae of inflammatory polyneuropathy (code range)
G90.50-G90.59	Complex regional pain syndrome I (code range)
M15.0-M15.9	Polyosteoarthritis (code range)
M16.0-M16.9	Osteoarthritis of hip (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M18.0-M18.9	Osteoarthritis of first carpometacarpal joint (code range)
M19.011-19.93	Osteoarthritis, shoulder, arm and hand (code range)
M34.83	Systemic sclerosis with polyneuropathy
M43.27	Fusion of spine, lumbosacral region
M43.28	Fusion of spine, sacral and sacrococcygeal region
M46.40-M46.49	Discitis, multiple sites (code range)
M47.10	Other spondylosis with myelopathy, site unspecified
M47.20	Other spondylosis with radiculopathy, site unspecified
M47.819	Spondylosis without myelopathy or radiculopathy, site unspecified
M47.899-M47.9	Spondylosis, unspecified (code range)
M48.00	Spinal stenosis, site unspecified
M50.00-M50.93	Cervical disc disorder with myelopathy, cervical region (code range)
M51.0 – M51.9	Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders
M53.2x7- M53.2x8	Spinal instabilities, lumbosacral and sacral sites (code range)
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies, lumbosacral sites (code range)
M54.11-M54.13	Radiculopathy, cervical area (code range)
M54.2	Cervicalgia
M54.30-M54.5	Sciatica, lumbago with sciatica, lumbago (code range)
M60.80-M60.9	Other myositis, specified site (code range)

Code	Description
M79.1	Myalgia
M79.7	Fibromyalgia
M96.1	Postlaminectomy syndrome, not elsewhere classified
R10.0-R10.9	Abdominal and pelvic pain (code range)

REFERENCES

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

Albornoz-Cabello M, et al. Effect of interferential current therapy on pain perception and disability level in subjects with chronic low back pain: A randomized controlled trial. Clin Rehabil. 2017;31(2):242-49.

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

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

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

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

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

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

Di Giorgi I, et al. The use of conventional transcutaneous electrical nerve stimulation in chronic facial myalgia patients. Clin Oral Investig 2017 Jan;21(1):275-280.

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

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

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

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

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

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

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

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

Kong X and Gozani SN. Effectiveness of fixed-site high-frequency transcutaneous electrical nerve stimulation in chronic pain: a large-scale, observational study. J Pain Res 2018 Apr 9;11:703-714.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Tan G, et al. Efficacy of cranial electrotherapy stimulation for neuropathic pain following spinal cord injury: a multi-site randomized controlled trial with a secondary 6-month open-label phase. The Journal of Spinal Cord Medicine 2011;34(3):285-296.

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

Upton GA, et al. The influence of transcutaneous electrical nerve stimulation parameters on the level of pain perceived by participants with painful diabetic neuropathy: a crossover study. Diabetes Metab Syndr 2017 Apr-Jun;11(2):113-118.

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

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

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

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

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

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

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

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

*Key Article

KEY WORDS

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

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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

LCD SITE: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33802&ver=32&CntrctrSelected=137*1&Cntrctr=137&s=41&DocType=Active&bc=AggAAAIAgAAA&=

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

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