Medical Coverage Policy | Transcutaneous Electrical Nerve Stimulation (TENS)

EFFECTIVE DATE: 07|01|2024
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OVERVIEW
Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin at the site of pain. TENS may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic).

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of TENS is considered medically necessary for treatment of chronic, intractable pain, acute post-operative pain or low back pain.

The use of TENS for any other condition, including but not limited to the treatment of dementia, management of essential tremor, management of attention deficit hyperactivity disorder, and prevention or treatment of migraine headaches, is not covered, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse (Axon Therapy) (e.g. Neuralace device) is considered not covered for all indications, including but not limited to chronic pain management, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
The use of TENS is considered medically necessary when filed with a covered indication (see Coding section below).

The use of TENS for any other condition, including but not limited to the treatment of dementia, management of essential tremor, management of attention deficit hyperactivity disorder, and prevention or treatment of migraine headaches, is considered not medically necessary, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse (Axon Therapy) (e.g. Neuralace device) is considered not medically necessary for all indications, including but not limited to chronic pain management, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable durable medical equipment benefits/coverage.

BACKGROUND

Transcutaneous electrical nerve stimulation (TENS) has been used to treat chronic intractable pain, migraine pain, postsurgical pain, and pain associated with active or post trauma injury unresponsive to other standard pain therapies. It has been proposed that TENS may provide pain relief through the release of endorphins in addition to potential blockade of local pain pathways. TENS has also been used to treat dementia by altering neurotransmitter activity and increasing brain activity that is thought to reduce neural degeneration and stimulate regenerative processes.

TENS devices consist of an electrical pulse generator, usually battery-operated, connected by wire to 2 or more electrodes, which are applied to the surface of the skin at the site of the pain. Since 1977, a large number of devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Marketing clearance via the 510(k) process does not require data on clinical efficacy; as a result, these cleared devices are considered substantially equivalent to predicate devices marketed in interstate commerce before May 1976, the enactment date of the Medical Device Amendments. The cleared devices are also equivalent to devices that have been reclassified and do not require a premarket approval application.

Chronic Pain

For individuals who have chronic pain (eg, musculoskeletal, neuropathic, and mixed pain conditions) who receive TENS, the evidence includes numerous randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and medication use. The overall strength of the evidence is weak. The best evidence exists for the treatment of chronic, intractable pain. Available evidence indicates that TENS can improve chronic intractable pain in some patients, and there is support for its use in clinical guidelines by specialty societies. To best direct TENS toward patients who will benefit, a short-term trial of TENS is appropriate, with continuation only in patients who show an initial improvement. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Attention Deficit Hyperactivity Disorder (ADHD)

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. This prescription only TENS device is indicated for patients 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 patient's forehead, just above the eyebrow.

For individuals who have ~~attention deficit hyperactivity disorder (~~ADHD~~)~~ who receive TENS, the evidence includes a ~~one~~ RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the RCT concluded that TENS is an effective and safe treatment option for pediatric patients with ADHD. However, the study included a small patient sample and was of short duration. 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.

Migraine Headaches

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. The Cefaly® Acute and Cefaly® Dual devices were cleared by the FDA through the 510(k) process for the acute treatment of migraine inpatients 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.

The evidence for the use of TENS for prevention of acute migraine in individuals with chronic or episodic migraine includes 1 RCT (N = 67) that reported a greater proportion of patients achieving at least a 50% reduction in migraines with TENS than with sham placebo. The RCT also reported modest reductions in the number of total headache and migraine days. This manufacturer-sponsored trial needs corroboration before conclusions can be made 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.

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.

Essential Tremor

In 2018, the FDA reviewed the Cala ONE™ TENS device (Cala Health) via the de novo pathway 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 patients with an implanted electrical medical device, those that have suspected or diagnosed epilepsy or other seizure disorder, those who are pregnant, and patients with swollen, infected, inflamed areas, or skin eruptions, open

wounds, or cancerous lesions. 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 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.

Isaacson et al (2020) evaluated the repeated home use of an FDA-cleared wrist-worn neuromodulation device in the Prospective Study for Symptomatic Relief of Essential Tremor with Cala Therapy (PROSPECT) trial. For each active treatment session, the device electrically stimulated the median and radial nerves for 40 minutes with an alternating burst pattern tuned to the frequency of each patient's tremor. The pre-specified co-primary endpoints were improvements on the clinician-rated Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) and patient-rated Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores. Of the 263 enrolled patients, 205 completed the visit 3 follow-up and were included in the primary analysis. Results revealed a significant improvement in TETRAS and BF-ADL from pre- to post-stimulation at each clinic visit ($p<.0001$ for all comparisons). Pre-stimulation tremor levels were improved from Visit 1 to 3 on both TETRAS and BF-ADL ($p<.0001$ for both). Patients rated as "severe" or moderate" improved with both TETRAS (49.3% at baseline to21% at study exit) and BF-ADL (64.8% at baseline to 23% at study exit) scoring. Tremor power is a calculation of amplitude and frequency. Tremor power decreases with lower amplitude motions and lower frequency motions. Tremor power was also noted to significantly improve with therapy from pre- to post-stimulation($p<.0001$). No device-related serious adverse events were reported. Non-serious device-related adverse events occurred in 18% of patients (eg, persistent skin irritation, sore/lesion, discomfort, electrical burns, and minor skin irritation). Conclusions were that the repeated in home use of this neuromodulation device over 3months was effective and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses.

For individuals who have essential tremor who receive TENS, 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 patients 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 end points, and exclusion of patients 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.

Dementia

TENS has also been used to treat dementia by altering neurotransmitter activity and increasing brain activity that is thought to reduce neural degeneration and stimulate regenerative processes. Input from physician specialty societies and academic medical centers were generally in agreement that TENS is investigational for the management of conditions such as dementia.

Other Conditions

A large number of systematic reviews, most conducted by Cochrane, have assessed the use of TENS in the treatment of a variety of pain conditions, including the topics of osteoarthritis, rheumatoid arthritis, pancreatitis, myofascial trigger points, temporomandibular joint pain, cancer pain, neck pain, acute pain, phantom limb pain, labor pain, and chronic back pain. In 2010, the American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders, including low back pain and diabetic peripheral neuropathy.

For individuals with low back pain and myofascial trigger points, available evidence suggests that TENS is ineffective. Available evidence from systematic reviews are inconclusive for cancer pain, osteoarthritis of the knee, rheumatoid arthritis, phantom knee pain, chronic neck pain, pain after stroke, and pain after spinal cord injury.

Transcutaneous Magnetic Stimulation (Axon Therapy)
Transcutaneous magnetic stimulation, or Axon Therapy, applies noninvasive neuromodulation by directing magnetic stimulation designed to activate a nerve that is causing ongoing pain post trauma. Axon Therapy non-invasively delivers focused magnetic pulses through a figure-8-shaped coil, targeting the damaged A-Beta sensory nerve fibers, proximal to the neuroma. By activating A-Beta, Axon Therapy helps modulate pain fiber activity at the site of trauma. Developed by NeuraLace Medical, Inc (San Diego, CA), the therapy was granted 510(k) clearance (K210021) in June 2021 by the FDA to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 and older.

Leung and colleagues (2014) stated peripheral nerve injury can result in the formation of neuroma/nerve entrapment, a persistent peripheral neuropathic pain state that is often refractory to invasive interventions or medications; thus, there is a need to develop innovative non-invasive therapy in treating post-traumatic peripheral neuropathic pain states. (106) A new intervention, transcutaneous magnetic stimulation (tMS), is derived from the use of transcranial magnetic stimulation in which a rapid discharge of electric current is converted into dynamic magnetic flux for modulating neuronal functions. In a case-series study, low-frequency (0.5 Hz) tMS was developed over the site of neuroma/nerve entrapment in 5 patients who have failed both steroid injection and conventional pain medications; 400 pulses of stimulation were delivered per treatment session. Each patient received 3 to 4 sessions of treatment over a period of 2 months. Pre- and post-intervention spontaneous pain levels were evaluated with Numeric Rating Scale (NRS); 5 patients with post-traumatic neuroma/nerve entrapment pain received the treatment. Average pre- and post-scores (± SD) on the NRS were 5.00 (± 1.41) and 0.80 (± 1.10), respectively, with an average pain reduction of 84 (± 21.91) % in the numerical rating pain scale (NRS) after 3 to 4 treatments within 2 months. This analgesic effect appeared to be sustainable with repeated treatment delivered at a 6- to 8-week duration. Pre-treatment tactile allodynia found in 3 patients resolved after the initial 2- month treatment sessions. The authors concluded that tMS offered a non-invasive therapeutic option for neuroma-related neuropathic pain conditions. Moreover, these researchers stated that RCTs are needed to validate the efficacy of this treatment modality; additional studies are also needed to examine the underlying electrophysiological mechanisms of the observed analgesic benefit. There are still ongoing and unpublished national clinical trials for Transcutaneous Magnetic Stimulation (Axon Therapy).

For individuals who have persistent peripheral neuropathic pain who receive transcutaneous magnetic stimulation, the evidence includes a single case-series study of 5 patients who had failed both steroid injection and conventional pain medications. Although results were encouraging, RCTs are needed to validate the efficacy of this treatment modality and to examine the underlying electrophysiological mechanisms of the observed analgesic benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Acute Pain
For individuals who have acute pain (eg, surgical, musculoskeletal, labor, and mixed pain conditions) who receive TENS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL , and medication use. Overall, evidence for the use of TENS from high-quality trials remains inconclusive for most indications. A systematic review of TENS for acute and chronic pain found some evidence that TENS reduces pain intensity over and above that seen with placebo and other control groups in patients with acute pain, but small-sized trials contributed to imprecision in magnitude estimates. Systematic reviews have found that TENS may help reduce pain in patients with post-operative pain (post-caesarean and total knee arthroplasty), dysmenorrhea, and pain associated with labor and delivery.

For low back pain, systematic reviews have found insufficient evidence to support or refute the use of TENS. Randomized controlled trials have reported mixed results in the efficacy of TENS across various acute pain conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans

The following code(s) are covered:

E0720 Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation

E0730 Transcutaneous electrical nerve stimulation (TENS) device, 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)

Commercial Products

The following code(s) are covered when filed with a covered diagnosis from the list below:

E0720 Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation

E0730 Transcutaneous electrical nerve stimulation (TENS) device, 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)

Covered ICD-10 diagnosis codes:

G89.21-G89.8
G90.50-G90.59
M25.50- M25.579
M54.10- M54.18
M54.2
M54.30-M54.32
M54.40-M54.42
M54.50 – M54.59
M54.6
M54.81, M54.89
M54.9
M79.10 – M79.18
M79.2
R52

Medicare Advantage Plans and Commercial Products

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

0766T Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve (Text Revised 1/01/2024)

0767T Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, 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) (Text Revised 1/01/2024)

E0733 Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve (New Code Effective 1/1/2024. For Dates of Service prior to 1/1/2024, HCPCS code K1016 must be used)

A4541 Monthly supplies for use of device coded at e0733 (New Code Effective 1/1/2024. For Dates of Service prior to 1/1/2024, HCPCS code K1017 must be used)
E0734 External upper limb tremor stimulator of the peripheral nerves of the wrist (New Code Effective 1/1/2024. For Dates of Service prior to 1/1/2024, HCPCS code K1018 must be used)
A4542 Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist (New Code Effective 1/1/2024. For Dates of Service prior to 1/1/2024, HCPCS code K1019 must be used)

RELATED POLICIES
Chiropractic Services

PUBLISHED
Provider Update, May 2024
Provider Update, July 2023
Provider Update, April 2022
Provider Update, April 2021
Provider Update, April 2020

REFERENCES

1. National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)
2. National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27)
3. National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13)
4. Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802). ~~Accessed April 17, 2023~~.
5. Food and Drug Administration. De Novo Classification Request for Cefaly Device. 2012; http://www.accessdata.fda.gov/cdrh_docs/reviews/K122566.pdf. Accessed September 24, 2023.
6. Food and Drug Administration. Cefaly Dual Device: K173006. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173006.pdf. Accessed September 25, 2023.
7. Food and Drug Administration. Cefaly Acute Device: K171446. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171446.pdf. Accessed September 26, 2023.
8. Food and Drug Administration. HeadaTerm Device: K172450. 2018; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172450.pdf. Accessed September 23, 2023.
9. Food and Drug Administration. Allive Device: K192773. 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192773.pdf. Accessed September 27, 2023.
10. Cala Health news release. Cala Health receives FDA breakthrough device designation for Cala Triotherapy to treat action tremors in Parkinson's disease. https://calahealth.com/uploads/pd-breakthrough-status.pdf. Accessed September 27, 2023.
11. FDA news release. FDA permits marketing of first medical device for treatment of ADHD. April 19, 2019. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-medical-device-treatment-adhd. Accessed September 27, 2023.
12. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). TENS or PENS in the treatment of chronic and postoperative pain. TEC Assessments. 1996; Volume 11, Tab 21.
13. Bronfort G, Nilsson N, Haas M, et al. Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. 2004(3):CD001878. PMID 15266458
14. Brosseau L, Judd MG, Marchand S, et al. Transcutaneous electrical nerve stimulation (TENS) for the treatment of rheumatoid arthritis in the hand. Cochrane Database Syst Rev. 2003(3):CD004377. PMID 12918009
15. Brosseau LU, Pelland LU, Casimiro LY, et al. Electrical stimulation for the treatment of rheumatoid arthritis. Cochrane Database Syst Rev. 2002(2):CD003687. PMID 12076504

16. Cameron M, Lonergan E, Lee H. Transcutaneous electrical nerve stimulation (TENS) for dementia. Cochrane Database Syst Rev. 2003(3):CD004032. PMID 12917999
17. Carroll D, Moore RA, McQuay HJ, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev. 2001(3):CD003222. PMID 11687055
18. Dowswell T, Bedwell C, Lavender T, et al. Transcutaneous electrical nerve stimulation (TENS) for pain relief in labour. Cochrane Database Syst Rev. 2009(2):CD007214. PMID 19370680
19. Hurlow A, Bennett MI, Robb KA, et al. Transcutaneous electric nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev. 2012;3:CD006276. PMID 22419313
20. Khadilkar A, Milne S, Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic low-back pain. Cochrane Database Syst Rev. 2005(3):CD003008. PMID 16034883
21. Khadilkar A, Odebiyi DO, Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. Cochrane Database Syst Rev. 2008(4):CD003008. PMID 18843638
22. Kroeling P, Gross A, Goldsmith CH, et al. Electrotherapy for neck pain. Cochrane Database Syst Rev. 2009(4):CD004251. PMID 19821322
23. Martimbianco ALC, Porfírio GJ, Pacheco RL, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic neck pain. Cochrane Database Syst Rev. Dec 12 2019; 12(12): CD011927. PMID 31830313
24. Milne S, Welch V, Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic low back pain.
25. Cochrane Database Syst Rev. 2001; (2): CD003008. PMID 11406059
26. Mulvey MR, Bagnall AM, Johnson MI, et al. Transcutaneous electrical nerve stimulation (TENS) for phantom pain and stump pain following amputation in adults. Cochrane Database Syst Rev. May 12 2010; (5): CD007264. PMID 20464749
27. Nnoaham KE, Kumbang J. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev. Jul 16 2008; (3): CD003222. PMID 18646088
28. Osiri M, Welch V, Brosseau L, et al. Transcutaneous electrical nerve stimulation for knee osteoarthritis. Cochrane Database Syst Rev. 2000; (4): CD002823. PMID 11034768
29. Price CI, Pandyan AD. Electrical stimulation for preventing and treating post-stroke shoulder pain. Cochrane Database Syst Rev. 2000; 2000(4): CD001698. PMID 11034725
30. Proctor ML, Smith CA, Farquhar CM, et al. Transcutaneous electrical nerve stimulation and acupuncture for primary dysmenorrhoea. Cochrane Database Syst Rev. 2002; 2002(1): CD002123. PMID 11869624
31. Robb KA, Bennett MI, Johnson MI, et al. Transcutaneous electric nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev. Jul 16 2008; (3): CD006276. PMID 18646140
32. Rutjes AW, Nüesch E, Sterchi R, et al. Transcutaneous electrostimulation for osteoarthritis of the knee. Cochrane Database Syst Rev. Oct 07 2009; 2009(4): CD002823. PMID 19821296
33. Walsh DM, Howe TE, Johnson MI, et al. Transcutaneous electrical nerve stimulation for acute pain. Cochrane Database Syst Rev. Apr 15 2009; (2): CD006142. PMID 19370629
34. Zimpel SA, Torloni MR, Porfírio GJ, et al. Complementary and alternative therapies for post-caesarean pain. Cochrane Database Syst Rev. Sep 01 2020; 9(9): CD011216. PMID 32871021
35. Dubinsky RM, Miyasaki J. 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. Jan 12 2010; 74(2): 173-6. PMID 20042705
36. Wu LC, Weng PW, Chen CH, et al. Literature Review and Meta-Analysis of Transcutaneous Electrical Nerve Stimulation in Treating Chronic Back Pain. Reg Anesth Pain Med. May 2018; 43(4): 425-433. PMID 29394211
37. Jalalvandi F, Ghasemi R, Mirzaei M, et al. Effects of back exercises versus transcutaneous electric nerve stimulation on relief of pain and disability in operating room nurses with chronic non-specific LBP: a randomized clinical trial. BMC Musculoskelet Disord. Mar 26 2022; 23(1): 291. PMID 35337314
38. Leemans L, Elma Ö, Nijs J, et al. Transcutaneous electrical nerve stimulation and heat to reduce pain in a chronic low back pain population: a randomized controlled clinical trial. Braz J Phys Ther. 2021; 25(1): 86-96. PMID 32434666

39. Keskin EA, Onur O, Keskin HL, et al. Transcutaneous electrical nerve stimulation improves low back pain during pregnancy. Gynecol Obstet Invest. 2012; 74(1): 76-83. PMID 22722614
40. Jamison RN, Wan L, Edwards RR, et al. Outcome of a High-Frequency Transcutaneous Electrical Nerve Stimulator (hfTENS) Device for Low Back Pain: A Randomized Controlled Trial. Pain Pract. Jun 2019; 19(5): 466-475. PMID 30636101
41. Gossrau G, Wähner M, Kuschke M, et al. Microcurrent transcutaneous electric nerve stimulation in painful diabetic neuropathy: a randomized placebo-controlled study. Pain Med. Jun 2011; 12(6): 953-60. PMID 21627767
42. Amer-Cuenca JJ, Badenes-Ribera L, Biviá-Roig G, et al. The dose-dependent effects of transcutaneous electrical nerve stimulation for pain relief in individuals with fibromyalgia: a systematic review and meta-analysis. Pain. Aug 01 2023; 164(8): 1645-1657. PMID 36893318
43. Dailey DL, Rakel BA, Vance CGT, et al. Transcutaneous electrical nerve stimulation reduces pain, fatigue and hyperalgesia while restoring central inhibition in primary fibromyalgia. Pain. Nov 2013; 154(11): 2554-2562. PMID 23900134
44. Lauretti GR, Chubaci EF, Mattos AL. Efficacy of the use of two simultaneously TENS devices for fibromyalgia pain. Rheumatol Int. Aug 2013; 33(8): 2117-22. PMID 23423539
45. Jamison RN, Edwards RR, Curran S, et al. Effects of Wearable Transcutaneous Electrical Nerve Stimulation on Fibromyalgia: A Randomized Controlled Trial. J Pain Res. 2021; 14: 2265-2282. PMID 34335055
46. Schneider MP, Tellenbach M, Mordasini L, et al. Refractory chronic pelvic pain syndrome in men: can transcutaneous electrical nerve stimulation help?. BJU Int. Jul 2013; 112(2): E159-63. PMID 23433012
47. Reichenbach S, Jüni P, Hincapié CA, et al. Effect of transcutaneous electrical nerve stimulation (TENS) on knee pain and physical function in patients with symptomatic knee osteoarthritis: the ETRELKA randomized clinical trial. Osteoarthritis Cartilage. Mar 2022; 30(3): 426-435. PMID 34826572
48. Cherian JJ, Harrison PE, Benjamin SA, et al. Do the Effects of Transcutaneous Electrical Nerve Stimulation on Knee Osteoarthritis Pain and Function Last?. J Knee Surg. Aug 2016; 29(6): 497-501. PMID 26540652
49. Palmer S, Domaille M, Cramp F, et al. Transcutaneous electrical nerve stimulation as an adjunct to education and exercise for knee osteoarthritis: a randomized controlled trial. Arthritis Care Res (Hoboken). Mar 2014; 66(3): 387-94. PMID 23983090
50. Vance CG, Rakel BA, Blodgett NP, 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. Jul 2012; 92(7): 898-910. PMID 22466027
51. Chen WL, Hsu WC, Lin YJ, et al. Comparison of intra-articular hyaluronic acid injections with transcutaneous electric nerve stimulation for the management of knee osteoarthritis: a randomized controlled trial. Arch Phys Med Rehabil. Aug 2013; 94(8): 1482-9. PMID 23628378
52. Sawant A, Dadurka K, Overend T, et al. Systematic review of efficacy of TENS for management of central pain in people with multiple sclerosis. Mult Scler Relat Disord. May 2015; 4(3): 219-27. PMID 26008938
53. Amatya B, Young J, Khan F. Non-pharmacological interventions for chronic pain in multiple sclerosis. Cochrane Database Syst Rev. Dec 19 2018; 12(12): CD012622. PMID 30567012
54. Johnson MI, Mulvey MR, Bagnall AM. Transcutaneous electrical nerve stimulation (TENS) for phantom pain and stump pain following amputation in adults. Cochrane Database Syst Rev. Aug 18 2015; 8(8): CD007264. PMID 26284511
55. Martins-de-Sousa PH, Fidelis-de-Paula-Gomes CA, Pontes-Silva A, et al. Additional effect of transcutaneous electrical nerve stimulation in a therapeutic exercise program for sedentary with chronic neck pain: A double-blind randomized controlled trial. Physiother Res Int. Jan 2023; 28(1): e1978. PMID 36252091
56. Díaz-Pulido B, Pérez-Martín Y, Pecos-Martín D, et al. Efficacy of Manual Therapy and Transcutaneous Electrical Nerve Stimulation in Cervical Mobility and Endurance in Subacute and Chronic Neck Pain: A Randomized Clinical Trial. J Clin Med. Jul 23 2021; 10(15). PMID 34362029

57. Boldt I, Eriks-Hoogland I, Brinkhof MW, et al. Non-pharmacological interventions for chronic pain in people with spinal cord injury. Cochrane Database Syst Rev. Nov 28 2014; (11): CD009177. PMID 25432061
58. De Giorgi I, Castroflorio T, Sartoris B, et al. The use of conventional transcutaneous electrical nerve stimulation in chronic facial myalgia patients. Clin Oral Investig. Jan 2017; 21(1): 275-280. PMID 27000071
59. de Castro-Carletti EM, Müggenborg F, Dennett L, et al. Effectiveness of electrotherapy for the treatment of orofacial pain: A systematic review and meta-analysis. Clin Rehabil. Jul 2023; 37(7): 891-926. PMID 36594219
60. Serrano-Muñoz D, Beltran-Alacreu H, Martín-Caro Álvarez D, et al. Effectiveness of Different Electrical Stimulation Modalities for Pain and Masticatory Function in Temporomandibular Disorders: A Systematic Review and Meta-Analysis. J Pain. Jun 2023; 24(6): 946-956. PMID 36801166
61. Ferreira AP, Costa DR, Oliveira AI, et al. Short-term transcutaneous electrical nerve stimulation reduces pain and improves the masticatory muscle activity in temporomandibular disorder patients: a randomized controlled trial. J Appl Oral Sci. 2017; 25(2): 112-120. PMID 28403351
62. Ahmed S, Plazier M, Ost J, et al. The effect of occipital nerve field stimulation on the descending pain pathway in patients with fibromyalgia: a water PET and EEG imaging study. BMC Neurol. Nov 12 2018; 18(1): 191. PMID 30419855
63. Takla MKN. Low-frequency high-intensity versus medium-frequency low-intensity combined therapy in the management of active myofascial trigger points: A randomized controlled trial. Physiother Res Int. Oct 2018; 23(4): e1737. PMID 30095858
64. Johnson MI, Paley CA, Jones G, et al. Efficacy and safety of transcutaneous electrical nerve stimulation (TENS) for acute and chronic pain in adults: a systematic review and meta-analysis of 381 studies (the meta-TENS study). BMJ Open. Feb 10 2022; 12(2): e051073. PMID 35144946
65. Gibson W, Wand BM, Meads C, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic pain – an overview of Cochrane Reviews. Cochrane Database Syst Rev. Apr 03 2019; 4(4): CD011890. PMID 30941745
66. Davison P, Wilkinson R, Miller J, et al. A systematic review of using electrical stimulation to improve clinical outcomes after hip fractures. Physiother Theory Pract. Dec 2022; 38(12): 1857-1875. PMID 33890541
67. Lang T, Barker R, Steinlechner B, et al. TENS relieves acute posttraumatic hip pain during emergency transport. J Trauma. Jan 2007; 62(1): 184-8; discussion 188. PMID 17215752
68. Zhu Y, Feng Y, Peng L. Effect of transcutaneous electrical nerve stimulation for pain control after total knee arthroplasty: A systematic review and meta-analysis. J Rehabil Med. Nov 21 2017; 49(9): 700-704. PMID 28933513
69. Hatefi F, Kazemi M, Manglian P, et al. The effects of cold compress and transcutaneous electrical nerve stimulation on the pain associated with chest tube removal among patients with coronary bypass grafting. J Cardiothorac Surg. May 25 2023; 18(1): 186. PMID 37231409
70. Ramanathan D, Saleh A, Klika AK, et al. The Use of Transcutaneous Electrical Nerve Stimulation After Total Knee Arthroplasty: A Prospective Randomized Controlled Trial. Surg Technol Int. Jul 25 2017; 30: 425-434. PMID 28537354
71. Parseliunas A, Paskauskas S, Kubiliute E, et al. Transcutaneous Electric Nerve Stimulation Reduces Acute Postoperative Pain and Analgesic Use After Open Inguinal Hernia Surgery: A Randomized, Double-Blind, Placebohttps: //www.bcbsaoca.com/eps/_w_c6a7b526/bcbsa_html/BCBSA/html/pol_1.01.09.html[2/28/2024 11:30:50 AM] Controlled Trial. J Pain. May 2021; 22(5): 533-544. PMID 33309784
72. Oztas B, Iyigun E. The effects of two different electrical stimulation methods on the pain intensity of the patients who had undergone abdominal surgery with a midline incision: Randomized controlled clinical trial. Contemp Nurse. 2019; 55(2-3): 122-138. PMID 31169066
73. Galli TT, Chiavegato LD, Liebano RE. Effects of TENS in living kidney donors submitted to open nephrectomy: a randomized placebo-controlled trial. Eur J Pain. Jan 2015; 19(1): 67-76. PMID 24831862

74. Tokuda M, Tabira K, Masuda T, et al. Effect of modulated-frequency and modulated-intensity transcutaneous electrical nerve stimulation after abdominal surgery: a randomized controlled trial. Clin J Pain. Jul 2014; 30(7): 565-70. PMID 24901753
75. Silva MB, de Melo PR, de Oliveira NM, et al. Analgesic effect of transcutaneous electrical nerve stimulation after laparoscopic cholecystectomy. Am J Phys Med Rehabil. Aug 2012; 91(8): 652-7. PMID 22311059
76. DeSantana JM, Walsh DM, Vance C, et al. Effectiveness of transcutaneous electrical nerve stimulation for treatment of hyperalgesia and pain. Curr Rheumatol Rep. Dec 2008; 10(6): 492-9. PMID 19007541
77. Forogh B, Aslanpour H, Fallah E, et al. Adding high-frequency transcutaneous electrical nerve stimulation to the first phase of post anterior cruciate ligament reconstruction rehabilitation does not improve pain and function in young male athletes more than exercise alone: a randomized single-blind clinical trial. Disabil Rehabil. Mar 2019; 41(5):514-522. PMID 29117738
78. Tucker DL, Rockett M, Hasan M, et al. Does transcutaneous electrical nerve stimulation (TENS) alleviate the pain experienced during bone marrow sampling in addition to standard techniques? A randomised, double-blinded, controlled trial. J Clin Pathol. Jun 2015; 68(6): 479-83. PMID 25759407
79. Binny J, Joshua Wong NL, Garga S, et al. Transcutaneous electric nerve stimulation (TENS) for acute low back pain: systematic review. Scand J Pain. Apr 24 2019; 19(2): 225-233. PMID 30849052
80. Koukoulithras I, Stamouli A, Kolokotsios S, et al. The Effectiveness of Non-Pharmaceutical Interventions Upon Pregnancy-Related Low Back Pain: A Systematic Review and Meta-Analysis. Cureus. Jan 30 2021; 13(1): e13011. PMID 33728108
81. Arik MI, Kiloatar H, Aslan B, et al. The effect of TENS for pain relief in women with primary dysmenorrhea: A systematic review and meta-analysis. Explore (NY). 2022; 18(1): 108-113. PMID 32917532
82. Guy M, Foucher C, Juhel C, et al. Transcutaneous electrical neurostimulation relieves primary dysmenorrhea: A randomized, double-blind clinical study versus placebo. Prog Urol. Jul 2022; 32(7): 487 -497. PMID 35249825
83. Platon B, Thörn SE, Mannheimer C, et al. Effects of high-frequency, high-intensity transcutaneous electrical nerve stimulation versus intravenous opioids for pain relief after hysteroscopy: a randomized controlled study. Obstet Gynecol Sci. Sep 2020; 63(5): 660-669. PMID 32717773
84. Lisón JF, Amer-Cuenca JJ, Piquer-Martí S, et al. Transcutaneous Nerve Stimulation for Pain Relief During Office Hysteroscopy: A Randomized Controlled Trial. Obstet Gynecol. Feb 2017; 129(2): 363-370. PMID 28079781
85. Deussen AR, Ashwood P, Martis R, et al. Relief of pain due to uterine cramping/involution after birth. Cochrane Database Syst Rev. Oct 20 2020; 10(10): CD004908. PMID 33078388
86. Thuvarakan K, Zimmermann H, Mikkelsen MK, et al. Transcutaneous Electrical Nerve Stimulation As A Pain-Relieving Approach in Labor Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Neuromodulation. Aug 2020; 23(6): 732-746. PMID 32691942
87. Kurata NB, Ghatnekar RJ, Mercer E, et al. Transcutaneous Electrical Nerve Stimulation for Post-Cesarean Birth https://www.bcbsaoca.com/eps/_w_c6a7b526/bcbsa_html/BCBSA/html/pol_1.01.09.html[2/28/2024 11:30:50 AM] Pain Control: A Randomized Controlled Trial. Obstet Gynecol. Aug 01 2022; 140(2): 174-180. PMID 35852266
88. Kayman-Kose S, Arioz DT, Toktas H, et al. Transcutaneous electrical nerve stimulation (TENS) for pain control after vaginal delivery and cesarean section. J Matern Fetal Neonatal Med. Oct 2014; 27(15): 1572-5. PMID 24283391
89. Báez Suárez A, Martín Castillo E, García Andújar J, et al. Evaluation of the effectiveness of transcutaneous nerve stimulation during labor in breech presentation: a case series. J Matern Fetal Neonatal Med. Jan 2021; 34(1): 24-30. PMID 30654675
90. Njogu A, Qin S, Chen Y, et al. The effects of transcutaneous electrical nerve stimulation during the first stage of labor: a randomized controlled trial. BMC Pregnancy Childbirth. Feb 24 2021; 21(1): 164. PMID 33627077

91. Goldman AR, Porsch L, Hintermeister A, et al. Transcutaneous Electrical Nerve Stimulation to Reduce Pain With Medication Abortion: A Randomized Controlled Trial. Obstet Gynecol. Jan 01 2021; 137(1): 100-107. PMID 33278292
92. Butera KA, George SZ, Borsa PA, et al. Prolonged Reduction in Shoulder Strength after Transcutaneous Electrical Nerve Stimulation Treatment of Exercise-Induced Acute Muscle Pain. Pain Pract. Nov 2018; 18(8): 954-968. PMID 29505689
93. Chesterton LS, Lewis AM, Sim J, et al. Transcutaneous electrical nerve stimulation as adjunct to primary care management for tennis elbow: pragmatic randomised controlled trial (TATE trial). BMJ. Sep 02 2013; 347: f5160. PMID 23999980
94. Isaacson SH, Peckham E, Tse W, et al. Prospective Home-use Study on Non-invasive Neuromodulation Therapy for Essential Tremor. Tremor Other Hyperkinet Mov (N Y). Aug 14 2020; 10: 29. PMID 32864188
95. McGough JJ, Sturm A, Cowen J, et al. Double-Blind, Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry. Apr 2019; 58(4): 403-411.e3. PMID 30768393
96. Singh RBH, VanderPluym JH, Morrow AS, et al. Acute Treatments for Episodic Migraine [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020 Dec. (Comparative Effectiveness Review, No. 239.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK566246/. Accessed November 6, 2023.
97. Ailani J, Burch RC, Robbins MS. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. Jul 2021; 61(7): 1021-1039. PMID 34160823
98. Tassorelli C, Diener HC, Silberstein SD, et al. Guidelines of the International Headache Society for clinical trials with neuromodulation devices for the treatment of migraine. Cephalalgia. Oct 2021; 41(11-12): 1135-1151. PMID 33990161
99. Diener HC, Tassorelli C, Dodick DW, et al. Guidelines of the International Headache Society for controlled trials of acute treatment of migraine attacks in adults: Fourth edition. Cephalalgia. May 2019; 39(6): 687-710. PMID 30806518
100. Chou DE, Shnayderman Yugrakh M, Winegarner D, et al. Acute migraine therapy with external trigeminal neurostimulation (ACME): A randomized controlled trial. Cephalalgia. Jan 2019; 39(1): 3-14. PMID 30449151
101. Hokenek NM, Erdogan MO, Hokenek UD, et al. Treatment of migraine attacks by transcutaneous electrical nerve stimulation in emergency department: A randomize controlled trial. Am J Emerg Med. Jan 2021; 39: 80-85. PMID 31983598
102. Domingues FS, Gayoso MV, Sikandar S, et al. Analgesic efficacy of a portable, disposable, and self-applied transcutaneous electrical nerve stimulation device during migraine attacks: A real-life randomized controlled trial. https://www.bcbsaoca.com/eps/_w_c6a7b526/bcbsa_html/BCBSA/html/pol_1.01.09.html[2/28/2024 11:30:50 AM] Pain Pract. Nov 2021; 21(8): 850-858. PMID 34013542
103. Schoenen J, Vandersmissen B, Jeangette S, et al. Migraine prevention with a supraorbital transcutaneous stimulator: a randomized controlled trial. Neurology. Feb 19 2013; 80(8): 697-704. PMID 23390177
104. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. Apr 04 2017; 166(7): 514-530. PMID 28192789
105. American Congress of Obstetricians and Gynecologists (ACOG) Committee Opinion Number 766 on Approaches to Limit Intervention During Labor and Birth. February 2019. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Approaches-to-Limit-Intervention-During-Laborand-Birth. Accessed September 27, 2023.
106. Benzon HT, Connis RT, De Leon-Casasola OA, et al. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain

Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010; 112(4): 810-33. PMID 20124882
107. National Cancer Institute. Pain (PDQ)-Health Professional Version. 2022. https://www.cancer.gov/aboutcancer/treatment/side-effects/pain/pain-hp-pdq#_3. Accessed September 27, 2023.
108. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain. Version 2.2023. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed September 27, 2023.
109. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management [NG59]. 2016 (last updated 2020); https://www.nice.org.uk/guidance/NG59. Accessed September 25, 2023.
110. National Institute for Health and Care Excellence (NICE). Osteoarthritis in over 16s: diagnosis and management [NG226]. 2022. https://www.nice.org.uk/guidance/ng226. Accessed September 26, 2023.
111. National Institute for Health and Care Excellence (NICE). Intrapartum care for healthy women and babies [CG190]. 2014 (last updated 2022); https://www.nice.org.uk/guidance/cg190. Accessed September 27, 2023. North American Spine Society. Diagnosis and Treatment of Low Back Pain. 2020. https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf. Accessed September 27, 2023.
112. Bono CM, Ghiselli G, Gilbert TJ, et al. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. Spine J. Jan 2011; 11(1): 64-72. PMID 21168100
113. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis Cartilage. Mar 2014; 22(3): 363-88. PMID 24462672
114. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. Nov 2019; 27(11): 1578-1589. PMID 31278997
115. Leung A, Fallah A, Shukla S. Transcutaneous magnetic stimulation (tMS) in alleviating post-traumatic peripheral neuropathic pain states: a case series. Pain Medicine 2014; 15:1196-1199. PMID 24666606
116. Food and Drug Administration. Axon Therapy. K210021. 2021; Available at https://www.accessdata.fda.gov. Accessed January 23, 2023.