BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

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Related Policies:

1.01.24 - Interferential Current Stimulation
2.01.21 - Temporomandibular Joint Disorder
7.01.29 - Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Transcutaneous Electrical Nerve Stimulation

Description

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Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin. In addition to more traditional settings such as a physician's office or an outpatient clinic, TENS can be self-administered in a patient's home.

OBJECTIVE

The objective of this evidence review is to determine whether the application of transcutaneous electrical nerve stimulation improves the net health outcome in individuals with a variety of health conditions including chronic and/or acute pain, essential tremor, and attention deficit hyperactivity disorder.

POLICY STATEMENT

A trial of transcutaneous electrical nerve stimulation (TENS) of at least 30 days may be considered **medically necessary** to establish efficacy for the management of refractory chronic pain (eg, chronic musculoskeletal pain or neuropathic pain) that causes significant disruption of function when the following conditions have been met:

- The pain is unresponsive to at least 3 months of conservative medical therapy; and
- The trial is monitored by a physician.

Continued use of TENS may be considered **medically necessary** for treatment of refractory chronic pain (eg, chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when the following conditions have been met:

- Efficacy has been demonstrated in an initial therapeutic trial (see Policy Guidelines section); and
- Compliance has been demonstrated in the therapeutic trial with the device used on a regular basis (eg, daily or near daily use) throughout the trial period.

TENS is considered **investigational** for the management of acute pain (eg, postoperative or during labor and delivery).

TENS is considered **investigational** for the prevention or treatment of migraine headache.

TENS is considered **investigational** for the management of essential tremor.

TENS is considered **investigational** for the management of attention deficit hyperactivity disorder.

The use of TENS for any other condition, including but not limited to the treatment of dementia is considered **investigational**.

POLICY GUIDELINES

For the purposes of these policy guidelines, refractory chronic pain is defined as pain that causes significant disruption of function and has not responded to at least 3 months of conservative therapy, including nonsteroidal anti-inflammatory medications, ice, rest, and/or physical therapy.

Documentation for the trial should include:

- Initial assessment/evaluation of the nature, duration, and perceived intensity of pain;
- The types and duration of prior treatments;
- Treatment plan including ongoing medications and proposed use of transcutaneous electrical nerve stimulation (TENS) unit, including the frequency and duration of treatment.

Clinical summary of the trial to determine efficacy should include:

- Perceived intensity of pain with and without TENS (eg, 2-point or 30% improvement in visual analog scale);
- Ongoing medication requirements for pain relief (if any);
- Other modalities (if any) in use for pain control;
- Actual use of TENS on a daily basis (frequency and duration of application).

TENS devices may be delivered through a practitioner and require a prescription, or obtained without a prescription. It is possible that prescribed devices provide higher intensity stimulation than units sold directly to the public.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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. FDA product code: GZJ.

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.[2,3,] 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.[4,5,6,]FDA product code: PCC.

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.[7,] 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.

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.[8,] 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.

In 2021, the FDA approved the Axon Therapy device (Neuralace Medical, Inc.) for marketing through the 510(k) process for relief of chronic, intractable postsurgical or posttraumatic pain in adults.[9,] The Axon Therapy device is an electromagnetic transcutaneous peripheral nerve stimulator. FDA product codes: QPL, IPF.

RATIONALE

Summary of Evidence

For individuals who have chronic pain (eg, musculoskeletal, neuropathic, and mixed pain conditions) who receive transcutaneous electrical nerve stimulation (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.

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.

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 endpoints, 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.

For individuals who have attention deficit hyperactivity disorder (ADHD) who receive TENS, the evidence includes an 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.

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" 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 Neurology

In 2010, the American Academy of Neurology published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders.[32,] The Academy did not recommend TENS for the treatment of chronic low back pain due to lack of proven efficacy (level A, established evidence from 2 class I studies), but stated that TENS should be considered for the treatment of painful diabetic neuropathy (level B, probably effective, based on 2 class II studies).

American College of Physicians

In 2017, the American College of Physicians published guidelines on noninvasive therapies for acute and low back pain.[101,] No recommendations for TENS were made; the College concluded that "evidence was insufficient to determine the effectiveness" of TENS and that there was no long-range data.

American Congress of Obstetricians and Gynecologists

In 2019 (reaffirmed in 2021), the ACOG guidelines on labor and delivery found that TENS may "help women cope with labor more than directly affect pain scores."[102,]

American Society of Anesthesiologists, et al

In 2010, the practice guidelines from the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine recommended that TENS be used as part of a multimodal approach to management for patients with chronic back pain and may be used for other pain conditions (eg, neck and phantom limb pain).[103,]

National Cancer Institute

The National Cancer Institute"s Physician Data Query identifies TENS as a potential nonpharmacological modality for pain control for postthoracotomy pain syndrome.[104,]

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on adult cancer pain (v 2.2023) indicate that nonpharmacologic interventions, including TENS, may be considered in conjunction with pharmacologic interventions as needed (category 2A).[105,]

National Institute for Health and Care Excellence

In 2016, the NICE guidance on low back pain indicated that, despite the long history of use of TENS for back pain, the quality of research studies is poor. This guidance recommended against TENS as a treatment.[106,]

In 2014, the NICE guidance on osteoarthritis care and management in adults indicated that TENS be considered "as an adjunct to core treatments for pain relief."[107,]

In 2017, the NICE guidance on intrapartum care recommended against the use of TENS for "established labour."[108,]

North American Spine Society

In 2020, the North American Spine Society clinical guidelines on the diagnosis and treatment of low back pain provided guidance on the effectiveness of different physical medicine and rehabilitation therapies.[109,] The guideline noted that there is conflicting evidence that TENS results in improvement in pain or function at short- to medium-term follow-up. The work group further recommended that randomized clinical trials with long-term follow-up are needed to evaluate the benefits of TENS compared to exercise/physical therapy or as adjunctive use to usual care for low back pain.

In 2011, the North American Spine Society clinical guidelines on the diagnosis and treatment of cervical radiculopathy from degenerative disorders discussed the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and TENS.[110,] A consensus statement from the Society recommended that ozone injections, cervical halter traction, and combinations of medications, physical therapy, injections, and traction have been associated with improvements in patient-reported pain in uncontrolled case series. Such modalities may be considered, recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated. There were no specific statements about the role of TENS in this population.

Osteoarthritis Research Society International

In 2014, the guidelines from the Osteoarthritis Research Society International recommended that TENS was inappropriate for use in patients with multi-joint osteoarthritis; moreover, the guidelines suggested that TENS has an uncertain value for the treatment of knee-only osteoarthritis pain.[111,] Updated guidance (2019) on the non-surgical management of knee, hip, and polyarticular osteoarthritis does not address TENS nor include it in their patient-focused treatment recommendations.[112,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently have a number of national coverage decisions on TENS.[113,114,115,] The different coverage decisions address the use of TENS in the treatment of chronic intractable pain, noncoverage of TENS for chronic low back pain except to conduct research for said indication, and coverage for acute postoperative pain.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	
December 2013	Replace policy	Policy updated with literature review, references 22, 24, 26, 32 35, 36 & 54 added. Policy statements are unchanged.
June 2014	Replace policy	Policy updated with literature review; References 1, 26-28, 3135, 45-48, 50-52 added; last policy statement revised to specifically list use of TENS in prevention of migraine headaches as not medically necessary.
June 2015	Replace policy	Policy updated with literature review. References 33, 43, and 45-46 added, and references 55-56 updated; policy statements unchanged.
June 2016	Replace policy	Policy updated with literature review through October 12, 2015 references 33-34, 50, and 52 added. Policy statements unchanged.
March 2018	Replace policy	Policy updated with literature review through September 12, 2017; references 33, 39-40, 49, and 55 added. Policy statements unchanged except "not medically necessary, corrected to "investigational, due to 510(k) status.
March 2019	Replace policy	Policy updated with literature review through September 18, 2018; references 25, 27-28, 51, and 63 added; references 72-74 updated. Policy statements unchanged.
March 2020	Replace policy	Policy updated with literature review through September 7, 2019, references added. Policy statements unchanged.
March 2021	Replace policy	Policy updated with literature review through October 7, 2020, references added. Policy statements unchanged.
March 2022	Replace policy	Policy updated with literature review through November 10, 2021, references added. Investigational policy statements for the use of specific TENS devices for essential tremor and ADHD indications added to policy.
March 2023	Replace policy	Policy updated with literature review through September 19, 2022, references added. Policy statements unchanged.
March 2024	Replace policy	Policy updated with literature review through September 27, 2023, references added. Removed outdated clinical input. Separated out evidence on migraine from the chronic pain and acute pain sections. Added new policy statement to clarify that TENS is investigational for both prevention and treatment of migraine headache. Other policy statements unchanged.