Medical Coverage Policy | Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation

EFFECTIVE DATE: 04|01|2025
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OVERVIEW

Transcutaneous electrical nerve stimulation and transcutaneous afferent patterned stimulation are noninvasive neuromodulation techniques that involve 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, these techniques can be self-administered in an individual's home.

MEDICAL CRITERIA

Medicare Advantage Plans

External Upper Limb Tremor Stimulator Therapy

External upper limb tremor stimulator therapy may be considered medically necessary when the medical criteria in the online authorization tool is met.

Commercial Products

Not applicable

PRIOR AUTHORIZATION

Medicare Advantage Plans

Prior authorization required for Medicare Advantage Plans for external upper limb tremor stimulator therapy. Refer to Coding section for details.

Commercial Products

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.

External Upper Limb Tremor Stimulator Therapy

External upper limb tremor stimulator therapy may be considered medically necessary when the medical criteria in the online authorization tool is met for participating providers.

External upper limb tremor stimulator therapy may be considered not covered when the medical criteria in the online authorization tool is not met.

The use of TENS for any other condition, including but not limited to the treatment of dementia, 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 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 afferent patterned stimulation (TAPS) is considered not medically necessary for the following conditions as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Essential tremor;
- Action tremor for Parkinson disease.

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. Transcutaneous afferent pattern stimulation (TAPS) is a similar treatment used for essential tremor and action tremor due to Parkinson disease.

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.

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. TAPS is a similar treatment used for essential tremor and action tremor due to Parkinson disease. The use of TENS or TAPS for the treatment of dementia is considered investigational.

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 (reaffirmed 2024), 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.

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. Cala Trio and Cala kIQ use transcutaneous afferent patterned stimulation (TAPS) therapy which consists of bursts of non-invasive electrical stimulation applied to the median and radial nerves.

Isaacson et al (2020) evaluated the repeated home use of an FDA-cleared wrist-worn TAPS 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 to 21% at study exit) and BF-ADL (64.8% at baseline to 23% at study exit) scoring. 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 3 months was effective and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses.

For individuals who have essential tremor who receive TAPS, the evidence includes a pragmatic RCT, a nonrandomized prospective study, and a retrospective database study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Although the RCT indicated reduced tremor power among patients receiving TAPS, the trial lacked thorough analysis of clinically relevant outcomes, was open-label, and short-term. Results from the nonrandomized study suggest that TAPS 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 TAPS 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.

Action Tremor Associated with Parkinson Disease

For individuals who have action tremor associated with Parkinson disease who receive TAPS, the evidence includes a prospective, open-label, single-arm study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the prospective trial suggest that repeated in-home TAPS therapy is effective for reducing tremor power and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, and lack of long-term outcomes. Further studies comparing TAPS to pharmacologic therapy for tremor associated with Parkinson disease are needed. 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)

The following code(s) are covered when medical criteria above is met:

E0734 External upper limb tremor stimulator of the peripheral nerves of the wrist

A4542 Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist

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

The following code(s) are not medically necessary:
E0734 External upper limb tremor stimulator of the peripheral nerves of the wrist
A4542 Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist

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
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)
E0733 Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
A4541 Monthly supplies for use of device coded at e0733

RELATED POLICIES
Chiropractic Services

PUBLISHED
Provider Update, March 2025
Provider Update, May 2024
Provider Update, July 2023
Provider Update, April 2022
Provider Update, April 2021

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