Medical Coverage Policy | Transcutaneous Electrical Nerve Stimulation (TENS)

EFFECTIVE DATE: 09|01|2023
POLICY LAST REVIEWED: 05|03|2023

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 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.

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 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.

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, 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 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) and HeadaTerm (EEspress) among others.

For the prevention of migraine headaches, a small RCT 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.

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.

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 transcutaneous electrical nerve stimulation (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 backpain. 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.

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:

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, July 2023
Provider Update, April 2022
Provider Update, April 2021
Provider Update, April 2020
Provider Update, January 2019

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