Medical Policy Reference Manual
Medical Policy

1.01.010 Transcutaneous Electrical Nerve Stimulators

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Description

Transcutaneous electrical nerve stimulators (TENS) are types of electronic devices that apply various amperages of electrical current to the surface of the skin at the site of pain and have been used to treat chronic intractable pain, post-surgical pain, and pain associated with active or post-trauma injury unresponsive to other standard pain therapies. TENS consists of an electrical pulse generator, usually battery-operated, connected by wire to 2 or more electrodes, which are applied to the surface of the skin at the site of the pain.

Examples of such devices include Alpha-Stim®, MicroStim®, MENS (microampere electrical nerve stimulator), Empi, interferential stimulator devices, and HANS (Han's Acupoint and Nerve Stimulator).

SCENAR (Self-controlled energo neuro-adaptive regulation), developed in Russia, is a variant of electroneural stimulation which sends out electrical impulses through the skin and interprets the response. It supposedly changes the impulse in accordance with the body's response in order to stimulate the body's self-healing properties. The SCENAR device was approved by the U.S. Food and Drug Administration (FDA) through the 510k process in 2009 for relief and management of chronic and acute pain, as adjunctive treatment in the management of post-surgical and post-traumatic pain. The U.S. FDA granted de novo 510(k) approval (March 11, 2014) for marketing to Cefaly® (STX-med, Herstal, Belgium), a TENS device for the prophylactic treatment of migraine in patients 18 years of age or older. A de novo premarket review pathway is generally used for low- to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device. The Nerivio Migra device was issued de novo clearance on November 6, 2018. It is marketed for acute treatment of migraine with or without aura in patients 18 years of age or older who do not have chronic migraine.

The HeadaTerm (EEspress) and the Allive (Nu Eyne Co) TENS devices were subsequently approved by the U.S. FDA in 2018 and 2019 through the 510(k) process as substantially equivalent to predicate devices. They are both indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

NOTE: This policy does not address TENS units used for the treatment of nausea and vomiting due to chemotherapy, motion sickness, and pregnancy (example: ReliefBand® NST™ Device). *(See Transcutaneous Electroneural Stimulation for Relief of Nausea and Vomiting, # 1.01.061)*

Policy

The use of TENS is considered **medically necessary** for painful diabetic neuropathy in cases where other pain control methods have failed.

The use of TENS is considered **experimental/investigational** for pain not related to diabetic neuropathy and for all other conditions, as it does not meet TEC criteria # 2 - 5.

The use of SCENAR is considered **experimental/investigational** for all indications as it does not meet TEC criteria # 2-5.

The use of the TENS devices (Cefaly®, HeadaTerm, Allive, and Nerivio) for migraine headaches is considered **experimental/investigational as** it does not meet TEC criteria # 2-5.

Policy Guidelines

Experimental/Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association (BCBSA) Medical Policy Services (MPS) Assessment Criteria (formerly known as the Technology Evaluation Center (TEC) are deemed to be experimental/investigational:

1. The technology* must have final approval from the appropriate U.S.[1] government regulatory bodies; and
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* Technology includes drugs, devices, processes, systems, or techniques

Footnote: [1]The BCBSA criteria indicates the technology must have final approval from the appropriate government regulatory bodies; however, CareFirst BlueCross BlueShield ("CareFirst") requires the technology receives final approval from the appropriate U.S. government regulatory body.

Rationale:

A review of the current literature concluded the effect of TENS units as a means of controlling pain or nausea and vomiting, is no more effective than a placebo.

2022 Update:

Nerivio device for migraine headaches:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

The Nerivio Migra device was issued De Novo clearance on November 6, 2018 (DEN180059). It is indicated for acute treatment of migraine with or without aura in patients 18 years of age or older who do not have chronic migraine.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The study described in the Nerivio Migra application for FDA clearance included 252 subjects. Inclusion criteria required subjects to be 18 through 75 years of age and have a history of 2-8 migraine attacks per month. During the first phase of the study participants were asked to keep a headache diary for one month. Participants were trained to use the smartphone app and headache diary during this time.

Participants next proceeded to the trial phase of the study. During this phase they were randomly allocated to one of two treatment groups: stimulation or sham. Participants in both groups underwent training to learn how to use the device to self-treat their migraines. Both groups were asked to treat their migraines using the device for 6 weeks or 4 qualified migraine attacks.

The Nerivio app was used to record pain scores at baseline, 2 hours post-treatment, and 48 hours post-treatment. The primary outcome measure was the percentage of participants in each group reporting pain reduction. Statistical comparisons determined whether the proportion was significantly different between the two treatment groups.

The proportion of participants who reported a reduction in pain 2 hours after treatment onset was 66.7% in the stimulation group and 38.8% in the sham group. The percentage of participants with at least 1 adverse event was 13.5% and was similar for the stimulation group and sham group. Adverse events included a sensation of warmth, numbness of the arm/hand, redness, and itching. No serious adverse events occurred.

3. The technology must improve the net health outcome:

The effect of this technology on net health outcome has not been documented in research studies.

4. The technology must be as effective as any established alternatives:

Several devices that provide electrical stimulation to treat headache are currently available. Studies to firmly establish the efficacy of such devices have not been performed. Comparisons between Nerivio and similar products have not been performed.

5. The improvement must be attainable outside the investigational settings:

No improvements have been demonstrated outside investigational settings.

2021 Update:
A search of the peer-reviewed literature was performed from the period of July 2019 through June 2021. Findings in the recent literature do not change the conclusions on the use of TENS. Therefore, the policy statements are unchanged.

2019 Update:
A search of the peer-reviewed literature was performed from the period of July 2017 through June 2019. Findings in the recent literature do not change the conclusions on the use of TENS. Therefore, the policy statements are unchanged.

2017 Update:
A search of the peer-reviewed literature was performed from the period of May 2015 through June 2017. Findings in the recent literature do not change the conclusions on the use of TENS. Therefore, the policy statements are unchanged.

2015 Update:
CEFALY® device for migraine headaches:

The U.S. FDA approval of the Cefaly device followed the agency's evaluation of the safety and effectiveness of the device based on data from a clinical study conducted in Belgium involving 67 individuals who experienced more than two migraine headache attacks a month and who had not taken any medications to prevent migraines for three months prior to using Cefaly, as well as a patient satisfaction study of 2,313 Cefaly users in France and Belgium. The 67-person study showed that those who used Cefaly experienced significantly fewer days with migraines per month and used less migraine attack medication than those who used a placebo device. The device did not completely prevent migraines and did not reduce the intensity of migraines that did occur.

A search of the peer-reviewed literature was performed for the period of April 2013 through April 2015. Findings in the recent literature do not change the conclusions on the use of TENS. Therefore, the policy statements are unchanged.

2013 Update:
A search of the peer-reviewed literature was performed for the period of June 2009 through March 2013. Findings in the recent literature do not change the conclusions on the use of TENS. Therefore, the policy statements are unchanged.

January 2011 Update:
It is important that any assessment of outcomes related to TENS technology be accomplished using only high quality, randomized controlled trials (RCT) preferably with double blinding. A considerable number of such studies have been published in the peer-reviewed literature for the typical uses of TENS: acute and chronic low back pain, knee pain, and cancer pain. These have been analyzed and reported on in systematic reviews. A Cochrane Systematic Review (Robb et al, 2009) concluded that there is insufficient available evidence to determine the effectiveness of TENS in treating cancer pain. Another Cochrane Systematic Review (Rutjes et al 2009) focused on pain from osteoarthritis of the knee. The authors identified poor methodological quality of the available studies and reporting methods as the reason for the inconclusive results of the review. The authors stated they could not confirm that TENS is effective for pain relief. Another Cochrane review (Walsh et al, 2009) reached a similar conclusion for acute pain in adults. The majority of evidence analyses were focused on chronic low back pain (LBP). A Cochrane review (Khadilkar et al, 2008) considered only high quality RCTs and generally found that based on multiple outcome measures, TENS provided no statistically significant improvement relative to placebo, and concluded that the evidence does not support the use of TENS in the routine management of chronic LBP. Hall and McIntosh (2008) reached similar conclusions in a 2008 meta-analysis, concluding that it is unknown whether TENS improves either symptoms or functional status based on evidence rated "very low" in quality. Finally, the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology published a report in 2010 concluding that TENS is established as "ineffective" for low back pain based on Class I evidence.

December 2011 Updates:
Use of TENS for treatment of painful diabetic peripheral neuropathy (DPN):

A search of the literature was undertaken to find clinical trials and / or consensus statements specific to the use of electrical stimulation to treat painful DPN. The current joint guideline of the American Academy of Neurology (AAN), American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation (Bril et al, 2011) cites a class I study that reports a significant degree of pain reduction from *percutaneous* electrical stimulation compared with a sham treatment, and two class II studies that demonstrated no pain relief or a small degree of relief with transcutaneous electrical stimulation. A consensus statement from the

Diabetes Research Unit of Royal Hallamshire Hospital and University of Sheffield, UK (Tesfaye et al, 2011) states that in extreme cases of painful DPN unresponsive to pharmacotherapy, occasional use of *spinal cord* stimulation may be indicated. A review by Pieber and colleagues of 15 studies (2010) suggested "consistent" effects of TENS on painful PDN. Four studies were focused on TENS, three of which were small randomized controlled trials, only one of which was blinded, and one retrospective analysis. Level of evidence was graded "B". Another small (n=22) randomized, placebo-controlled study (Gossrau et al, 2011) concluded the pain reduction from TENS therapy is not superior to placebo treatment. A meta-analysis by Jin and colleagues (2010) concluded that TENS may be safe and effective, but that large, multicenter randomized controlled trials are needed to further evaluate the long-term effect of TENS on DPN. The AAN's report on the efficacy of TENS in the treatment of pain in neurologic disorders concluded that TENS is "probably" effective in reducing pain associated with DPN based on Level B Class II studies.

SCENAR interactive neurostimulation:

SCENAR (Self-controlled energo neuro-adaptive regulation) is a variant of electroneural stimulation developed in Russia for the Russian space program. The mechanism of action of the SCENAR is described as "reflex biofeedback". According to their web site, the SCENAR sends out electrical impulses through the skin and interprets the response, then changes the impulse in accordance with the body's response, the end result being to stimulate the body's self-healing properties. No action on the part of the patient is required.

It should be noted that in Europe where the SCENAR devices are popular, the devices are promoted within the alternative medicine community as useful to promote overall good health and wellbeing, as well as a treatment for a variety of medical conditions other than chronic pain.

2009 Update:
A search of the peer-reviewed literature was performed for the period of February 2007 through May 2009. Findings in the recent literature do not change the conclusions on the use of TENS. Therefore, the policy statement is unchanged.

2007 Update:
A search of the peer-reviewed literature was performed for the period of April 2005 through January 2007. Findings in the recent literature do not change the conclusions on the use of TENS, therefore, the policy statement is unchanged.

Benefit Applications

The purpose of this Medical Policy Reference Manual is to provide clinical criteria and/or local, state, or federal coverage requirements for applicable services, devices, and drugs. Specific contract provisions, restrictions, and exclusions will take precedence over the clinical criteria, as the member contract supersedes clinical criteria adopted by CareFirst. Always check the member's contract for benefits. Benefits are not provided for lead wires or supplies (examples: replacement electrodes, replacement batteries, paste) for transcutaneous electrical nerve stimulator units (TENS), except when device meets clinical criteria for the treatment of painful diabetic neuropathy as indicated in this policy.

Provider Guidelines

There are no Provider Guidelines for this Medical Policy.

Cross References to Related Policies and Procedures

1.01.005	H-Wave Electrical Stimulation Devices for Home Use, Policy
1.01.017	Pulsed Electrical Stimulation Device for Osteoarthritis of the Knee, Policy
1.01.018	Neuromuscular Electrical Stimulation (NMES) Devices, Policy
1.01.061	Transcutaneous Electroneural Stimulation for Relief of Nausea and Vomiting, Policy
2.01.060	Electromagnetic and Electrical Stimulation for the Care of Chronic Wounds, Policy
3.01.013	Transcranial Magnetic Stimulation for Treatment of Depression and Other Psychiatric/Neurologic Disorders, Policy
7.01.023	Percutaneous Electrical Nerve Stimulation (PENS), Policy
8.01.001	Physical Therapy, Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability

or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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UptoDate. Management of knee osteoarthritis (March 26, 2019; Feb 26, 2021). Authors: Deveza, L.A., Bennell, K.

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