

Corporate Medical Policy

TENS (Transcutaneous Electrical Nerve Stimulator)

File Name: tens_(transcutaneous_electrical_nerve_stimulator)
Origination: 7/1982
Last CAP Review: 4/2020
Next CAP Review: 4/2021
Last Review: 4/2020

Description of Procedure or Service

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).

TENS has 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. It has been proposed that TENS may provide pain relief through 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. Percutaneous electrical nerve stimulation is similar to TENS, but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation uses a modulated waveform for deeper tissue stimulation, and is believed to improve blood flow to the affected area.

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 received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy; these devices are considered substantially equivalent to predicate devices marketed in interstate commerce prior to May 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified and do not require approval of a premarket approval application (PMA).

Note: 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.

On March 11, 2014 FDA granted de novo 510(k) approval for marketing to Cefaly® (STX-Med, Herstal, Belgium), which is a TENS device for the prophylactic treatment of migraine in patients 18 years of age or older.

The Scrambler Therapy MC-5A TENS device (Competitive Technologies, Inc., Fairfield, CT) was approved by the FDA 510(k) process in 2009 and classified as a multichannel TENS that allows simultaneous treatment of a number of pain sites. It is indicated for "symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain".

Related Policies:

Durable Medical Equipment (DME)
Interferential Stimulation

TENS (Transcutaneous Electrical Nerve Stimulator)

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for TENS (transcutaneous electrical nerve stimulator) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When TENS (Transcutaneous Electrical Nerve Stimulation) is covered

- A. An initial 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 (more than 3 to 6 months: 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 including physical therapy; AND
 - The trial is monitored by a physician as supported by medical record documentation
- B. Continued use of transcutaneous electrical nerve stimulation (TENS) beyond the 1 month trial period may be considered **medically necessary** for treatment of refractory chronic pain (more than 3 to 6 months: chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when the following conditions have been met:
1. Efficacy has been demonstrated in an initial therapeutic trial (see policy guidelines); AND
 2. Compliance continues to be met with at least near daily use as monitored and documented by a physician as supported by the medical record; AND
 3. For continued use beyond 12 months, compliance continues to be met with at least near daily use as monitored and documented by a physician every three months and supported by the medical record

When TENS (Transcutaneous Electrical Nerve Stimulation) is not covered

TENS is considered not medically necessary for the management of refractory chronic pain when the criteria above are not met.

TENS is considered **investigational** for the management of acute pain (less than 3 months duration: for example, acute postoperative or during labor and delivery).

TENS is considered investigational for other conditions including but not limited to acute and chronic headaches, migraine, temporomandibular joint dysfunction (tmj), dementia, chest pain, fibromyalgia, pain in burns, chemotherapy induced neuropathy, amputation pain (phantom pain), pelvic pain, post joint replacement pain, pelvic pain, ADHD, and tremor.

Transcutaneous electrical modulation pain reprocessing (Scrambler therapy with use of the Calmare® pain therapy device) is considered investigational for all indications.

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Reimbursement

Summary of reimbursement for supplies for medically necessary TENS Units (E0720 or E0730).

Separate allowance is made for medically necessary replacement supplies used with a purchased TENS unit.

- Reimbursement for TENS supplies is limited to one unit of A4595 per month for a 2-lead TENS (12) and two units of A4595 per month for a 4-lead TENS (24)
- Replacement of damaged lead wires (A4557) is rarely medically necessary more frequently than every 12 months; therefore, reimbursement for code A4557 is limited to one (1) unit per 12-month period

Reimbursement for A4595 includes the following and cannot be billed separately:

- Electrodes (any type) (A4556)
- Conductive past or gel (if needed, depends on the type of electrode used) (A4558)
- Tape or other adhesive (if needed) (A4364)
- Adhesive removal, skin preparation materials (A4455)
- Batteries (9 volt or AA, single use or rechargeable) (A4630)
- Battery charger (if rechargeable batteries are used).
- Other Supplies: No separate or additional reimbursement is made for the following supply items:
 - Adapters (i.e., snap, banana, alligator, tab, button, clip)
 - Belt clips
 - Adhesive remover
 - Additional connection cable for lead wires
 - Carrying pouches or covers.

Policy Guidelines

Refractory chronic pain is defined in this policy as pain that causes significant disruption of function and has not responded to at least 3 months of conservative therapy, including other interventional treatments, medications (neurolectics, non-opioid, opioid) , bracing, and physical therapy.

Documentation for the trial period of at least 1 month should include:

- Initial assessment/evaluation of the specific type of pain condition: nature, duration, and perceived intensity of pain;
- The types and duration of prior treatments including medication, bracing, physical therapy;
- Treatment plan including ongoing medications and proposed use of TENS unit, including the frequency and duration of treatment.

Clinical summary of the trial after at least 1 month as monitored by a physician and documented in the medical record to determine efficacy includes:

- Improved perceived intensity of pain with TENS as documented with a 2 point or 30% improvement in visual analog scale [VAS] or similar objective pain scale
- Ongoing medication requirements for pain relief (reduction of prior medication use)
- Other treatments in use for pain control (reduced interventional treatments);
- Improved functional status
- Actual use of TENS on a daily basis (frequency and duration of application) to determine compliance of device use

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For continued use of the TENS, ongoing monitoring and documentation by the physician every 3 months to determined continued use and efficacy of pain reduction.

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.

Summary of Evidence

For individuals who have chronic pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions) who receive TENS, the evidence includes numerous RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The overall strength of the evidence is weak. The best evidence exists for 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 a meaningful improvement in the net health outcome.

For individuals who have acute pain (e.g., surgical, musculoskeletal, labor, and mixed pain conditions) who receive TENS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms and medication use. Overall, evidence for the use of TENS from high-quality trials remains inconclusive for most indications. A Cochrane review of TENS for acute pain (e.g., cervical laser treatment, venipuncture, screening flexible sigmoidoscopy, postpartum uterine contractions, rib fractures) found some evidence that TENS reduces pain intensity over and above that seen with placebo, but the high risk of bias made definitive conclusions impossible. For the treatment of pain after total knee arthroplasty, 2 large RCTs found no benefit of TENS compared with sham TENS. A subsequent systematic review found that TENS reduced pain in the immediate postoperative period (24 hours) after total knee arthroplasty compared with control intervention, however, neither the intensity nor optimal duration time for TENS have been established. 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, and 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. For the relief of pain during office-based hysteroscopy, an RCT found decreased pain and higher patient satisfaction in patients receiving TENS compared with placebo or control. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: A4557, A4595, A4630, E0720, E0730, E0731, K1016- K1019, 64550, 0278T

There is no specific coding for the Cefaly device. It would most likely be reported with the miscellaneous durable medical equipment code E1399.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 11/96

Medical Policy Advisory Group - 1/99

Specialty Matched Consultant Advisory Panel - 9/2000

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual - 2/15/2002; 1.04.03

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 12/18/2002

Specialty Matched Consultant Advisory Panel - 6/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 12/14/2005

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 7/9/2009

Senior Medical Director - 5/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 8/12/2010

Specialty Matched Consultant Advisory Panel – 11/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 8/11/2011

Specialty Matched Consultant Advisory Panel – 11/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 8/9/2012

Specialty Matched Consultant Advisory Panel review – 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 7/13/2013

Specialty Matched Consultant Advisory Panel – 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 4/10/2014

Senior Medical Director – 5/2014

U.S. Food and Drug Administration. De Novo Classification Request for Cefaly Device. 2012. Available online at: http://www.accessdata.fda.gov/cdrh_docs/reviews/K122566.pdf. Last accessed October, 2014.

Specialty Matched Consultant Advisory Panel - 10/2014

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 4/23/2015

Specialty Matched Consultant Advisory Panel - 10/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/12/2015

Specialty Matched Consultant Advisory Panel - 10/2016

Majithia, N., Smith, T. J., Coyne, et.al.(2016). Scrambler Therapy for the management of chronic pain. *Supportive Care in Cancer : Official Journal of the Multinational Association of Supportive Care in Cancer*, 24(6), 2807–2814. <http://doi.org/10.1007/s00520-016-3177-3>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/14/2019

Specialty Matched Consultant Advisory Panel - 4/2020

Policy Implementation/Update Information

7/82	Original Policy: Generally accepted medical practice for acute postoperative pain and chronic intractable pain
8/83	Reaffirmed
6/84	Reaffirmed
8/88	Reviewed: Eligible for coverage for acute postoperative pain and chronic intractable pain; use for pain of labor and vaginal delivery consideration is investigational
2/97	Reaffirmed - National Association reviewed 11/30/96
1/99	Reaffirmed. Medical Policy Advisory Group. Added E0720 and E0730
8/99	Reformatted, Medical Term Definitions added.
10/00	Specialty Matched Consultant Advisory Panel (two). No change recommended in criteria. Medical Policy Advisory Group review. No change in criteria. Approve.
6/01	Added the following statement under the noncovered indications "Sequential stimulators which act to relieve pain and restore muscle function would be considered a "deluxe" model of TENS. They are not covered." A4595 and E0731 added to coding with format change.
7/01	Policy name changed from Transcutaneous Electrical Nerve Stimulator (TENS) to TENS (Transcutaneous Electrical Nerve Stimulator).
5/02	Policy revised under when it is not covered to include sympathetic therapy as investigational. Format changes.
8/02	Specialty Matched Consultant Advisory Panel review 7/12/2002. No changes.
09/02	System coding changes.
11/03	The following statement was added to Description section, "For Interferential Stimulation, please see policy DME0155 entitled Interferential Stimulation." No changes to the policy.
4/8/04	Removed statement referring to sequential stimulators as deluxe models. Added information referring reader to Interferential Stimulator policy for information regarding the Sequential Stimulator. Billing/Coding section updated for consistency.

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- 7/29/04 Specialty Matched Consultant Advisory Panel review 6/22/2004. Removed statement from When Transcutaneous Electrical Nerve Stimulation is covered indicating "When covered, it will be on the basis of individual consideration." Benefit Application section format updated for consistency. References added. Notification given 7/29/2004. Effective 10/14/2004.
- 6/5/06 Specialty Matched Consultant Advisory Panel review 5/3/2006. No changes to policy statement. References added.
- 9/18/06 Added statement "Note: Form-fitting conductive garments used with TENS are considered a convenience item and are not covered." to the "When Not Covered" section. Policy status changed to Active Archive, policy no longer scheduled for routine literature review. (btw)
- 6/22/10 Policy status returned to active, converted from Corporate Medical Policy to Evidence Based Guideline. "Description" section revised. Evidence Based Guideline indicates; "A trial of transcutaneous electrical nerve stimulation (TENS) of at least 30 days may be appropriate to establish efficacy for the management of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function The pain is unresponsive to at least 3 months of conservative medical therapy; AND The trial is monitored by a physician." "Continued use of transcutaneous electrical nerve stimulation (TENS) may be appropriate for treatment of refractory chronic pain (e.g., 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); AND Compliance has been demonstrated in the therapeutic trial with the device used on a regular basis (e.g., daily or near daily use) throughout the trial period." "TENS is not recommended for the management of acute pain (e.g., postoperative or during labor and delivery)." "The use of TENS for any other condition, including the treatment of dementia, is not recommended." Removed HCPCS code E0731, since this is a non-covered item. Reviewed with Senior Medical Director 5/26/2010. References added. (btw)
- 12/21/10 Specialty Matched Consultant Advisory Panel review 11/21/2010. No change to guideline intent. The following information was moved from the "Benefits Guidelines" section to Evidence Based Guideline section; "Refractory chronic pain is defined in this guideline 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." And "Overall, evidence for the use of TENS from high quality trials remains inconclusive. However, clinical input indicates that the use of TENS for the relief of chronic intractable pain has been beneficial in some patients. Therefore, the guideline has been revised; TENS may be recommended for the treatment of chronic pain if shown to be effective during a 30 day therapeutic trial." Moved statement indicating "TENS devices may be delivered through a practitioner and requires a prescription, or obtained without a prescription. It is possible that prescribed devices provide higher intensity stimulation than units sold directly to the public." To "Description" section. References to "medical policy" changed to either "evidence based guideline" or "guideline" as appropriate. References added. (btw)
- 10/11/11 Reference added. (btw)
- 1/1/12 Specialty Matched Consultant Advisory Panel review 11/30/11. "Evidence Based Guideline" reformatted. No change to guideline. Added 2012 CPT code, 0278T, to the "Billing/Coding" section. (btw)
- 10/16/12 Reference added. (btw)
- 8/27/13 Reference added. (btw)

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- 11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to guideline. (btw)
- 11/11/14 Evidence based guideline converted to corporate medical policy. Added information to the Description section regarding Cefaly. Added information to the When Not Covered section to advise that TENS for the prevention of migraine headaches is considered investigational. Policy Guidelines updated. Senior Medical Director review 10/2014. Reference added. Notification given 11/11/14. Policy effective 01/13/15. (sk)
- 3/10/15 Specialty Matched Consultant Advisory Panel review 10/28/2014. No change to Policy statement. (sk)
- 7/1/15 Reference added. (sk)
- 11/24/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. (sk)
- 1/26/16 Reference added. Policy Guidelines updated. (sk)
- 11/22/16 Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)
- 5/26/17 Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (an)
- 7/26/17 Description Section updated to include information on Scrambler Therapy. The following was added to the When TENS is Not Covered: Transcutaneous electrical modulation pain reprocessing (Scrambler therapy with use of the Calmare[®] pain therapy device) is considered investigational for all indications. Policy Guidelines section updated. Reference added. **Notification given 7/26/2017 for policy effective date 9/29/2017.** (an)
- 6/8/18 Reference added. Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy statement. (an)
- 4/30/19 Updated Policy Guidelines section. Reference added. Specialty Matched Consultant Advisory Panel review 4/17/2019. No change to policy statement. (an)
- 3/31/20 Reimbursement section added and now includes supply limits. Policy guidelines updated. Updated when not covered section with a list of non-covered indications and conditions. When covered section bullet “B. → 3.” added. Coding section updated. **Notification given 3/31/2020 for policy effective date 6/9/2020.** (eel)
- 6/9/20 Reference added. Specialty Matched Consultant Advisory Panel review 4/15/2020. No change to policy statement. (eel)
- 3/31/21 When not covered section updated to include ADHD and tremor. Added 2021 HCPCS codes K1016-K1019 to the “Billing/Coding” section effective 4/1/2021. Medical director review. No change to policy statement. (bb)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational

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purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.