Corporate Medical Policy

TENS (Transcutaneous Electrical Nerve Stimulator)

File Name: tens_transcutaneous_electrical_nerve_stimulator
Origination: 7/1982
Last Review: 4/2023

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.

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) and HeadaTerm (EEspress) among others.4,5,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.

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.

Related Policies:
Durable Medical Equipment (DME)
Interferential Stimulation
Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy
Temporomandibular Joint Disorder

******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:
    1. The pain is unresponsive to at least 3 months of conservative medical therapy including physical therapy; AND
    2. 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, termporomandibular 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.

Chronic pain management with the use of Axon Therapy is considered investigational.

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

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 (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 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.

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: *A4540, A4541, A4542, A4557, A4595, A4630, E0720, E0730, E0731, E0733, E0734, 0278T, 0766T, 0767T, 97014, 97032*

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.

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

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/12/2021

Specialty Matched Consultant Advisory Panel 4/2021

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National Institute for Health and Care Excellence (NICE). Osteoarthritis: care and management [CG177]. 2014. Updated December 2020. https://www.nice.org.uk/guidance/cg177. Accessed November 10, 2021.

National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management [NG59]. 2016 (last updated 2020); https://www.nice.org.uk/guidance/NG59. Accessed November 9, 2021.

National Institute for Health and Care Excellence (NICE). Intrapartum care for healthy women and babies [CG190]. 2014 (last updated 2017); https://www.nice.org.uk/guidance/cg190. Accessed November 8, 2021.

Specialty Matched Consultant Advisory Panel 4/2022

Medical Director review 4/2022

Medical Director review 11/2022

Cala Health news release. Cala Health receives FDA breakthrough device designation for Cala Trio therapy to treat action tremors in Parkinson's disease. https://calahealth.com/uploads/pd-breakthrough-status.pdf.

FDA news release. FDA permits marketing of first medical device for treatment of ADHD. April 19, 2019. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-medical-device-treatment-adhd.

Specialty Matched Consultant Advisory Panel 4/2023

Medical Director review 4/2023

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.

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)

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 202**1** HCPCS codes K1016-K1019 to the "Billing/Coding" section effective 4/1/2021. Medical director review. No change to policy statement. (bb)

5/18/21 Reference added. Specialty Matched Consultant Advisory Panel review 4/2021. Medical Director review 4/2021. No change to policy statement. (bb)

11/2/21 Added 2021 HCPCS codes K1023 to the "Billing/Coding" section. (tt)

5/3/22 Regulatory status updated. References added. Specialty Matched Consultant Advisory Panel review 4/2022. Medical Director review 4/2022. No change to policy statement. (tt)

7/12/22 Removed code 64550. Added codes 97014 and 97032. No changes to policy statement or intent (tt)

12/30/22 Added the following statement to When Not Covered section, "Chronic pain management with the use of Axon Therapy is considered investigational." Updated Billing/Coding section to add 0766T, 0767T, 0768T, 0769T, effective 1/1/2023. Medical Director review 11/2022. (tt)

5/2/23 Policy guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 4/2023. Medical Director review 4/2023. No change to policy statement. (tt)

12/29/23 Removed HCPCS codes K1016-K1019, K1023 and CPT codes 0768T and 0769T from Billing/Coding section. Added CPT codes A4540, A4541, A4542, E0733, and E0734 to Billing/Coding section, effective 1/1/2024. (tt)