TENS (Transcutaneous Electrical Nerve Stimulator)

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:
Interferential Stimulation
Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy
TENS (Transcutaneous Electrical Nerve Stimulator)

***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 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 (e.g., 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; AND
- The trial is monitored by a physician.

Continued use of transcutaneous electrical nerve stimulation (TENS) may be considered medically necessary 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.

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 (e.g., postoperative or during labor and delivery).

The use of TENS for any other condition, including but not limited to the treatment of dementia and prevention of migraine headaches, is considered investigational.

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

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 nonsteroidal anti-inflammatory medications, ice, rest, and/or physical therapy.

Documentation for the trial should include:
TENS (Transcutaneous Electrical Nerve Stimulator)

- Initial assessment/evaluation of the nature, duration, and perceived intensity of pain;
- The types and duration of prior treatments;
- Treatment plan including ongoing medications and proposed use of TENS unit, including the frequency and duration of treatment.

Clinical summary of the trial to determine efficacy should include:

- Perceived intensity of pain with and without TENS (e.g., 2 point or 30% improvement in visual analog scale [VAS]);
- Ongoing medication requirements for pain relief (if any);
- Other modalities (if any) in use for pain control;
- Actual use of TENS on a daily basis (frequency and duration of application).

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.

The evidence for TENS in individuals who have chronic pain includes numerous randomized controlled trials (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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for TENS in individuals who have acute pain 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 (eg, 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, 1 large RCT found no benefit of TENS compared with sham TENS. For the prevention of migraine headaches, 1 small RCT reported a greater proportion of patients achieving at least 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

There is insufficient evidence in the published peer reviewed scientific literature to support the efficacy of transcutaneous electrical modulation pain reprocessing (TEMPR). Studies comparing TEMPR to conventional treatment options and to sham therapy are lacking. Available studies are primarily in the form of case series with small, heterogeneous patient populations and short-term follow-ups investigating TEMPR for the treatment of various types of pain. Also, there are no clinical practice guidelines recommending scrambler therapy. 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.
TENS (Transcutaneous Electrical Nerve Stimulator)

Applicable codes: A4595, A4630, E0720, E0730, E0731, 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.

Scientific Background and Reference Sources

Senior Medical Director - 5/2010
Specialty Matched Consultant Advisory Panel review – 10/2012
TENS (Transcutaneous Electrical Nerve Stimulator)


Senior Medical Director – 5/2014


Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Details</th>
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<tbody>
<tr>
<td>7/82</td>
<td>Original Policy: Generally accepted medical practice for acute postoperative pain and chronic intractable pain</td>
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<tr>
<td>8/83</td>
<td>Reaffirmed</td>
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<tr>
<td>6/84</td>
<td>Reaffirmed</td>
</tr>
<tr>
<td>8/88</td>
<td>Reviewed: Eligible for coverage for acute postoperative pain and chronic intractable pain; use for pain of labor and vaginal delivery consideration is investigational</td>
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<tr>
<td>2/97</td>
<td>Reaffirmed - National Association reviewed 11/30/96</td>
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<tr>
<td>8/99</td>
<td>Reformatted, Medical Term Definitions added.</td>
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<tr>
<td>6/01</td>
<td>Added the following statement under the uncovered indications &quot;Sequential stimulators which act to relieve pain and restore muscle function would be considered a &quot;deluxe&quot; model of TENS. They are not covered.&quot; A4595 and E0731 added to coding with format change.</td>
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<tr>
<td>7/01</td>
<td>Policy name changed from Transcutaneous Electrical Nerve Stimulator (TENS) to TENS (Transcutaneous Electrical Nerve Stimulator).</td>
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<tr>
<td>5/02</td>
<td>Policy revised under when it is not covered to include sympathetic therapy as investigational. Format changes.</td>
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<tr>
<td>09/02</td>
<td>System coding changes.</td>
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<tr>
<td>11/03</td>
<td>The following statement was added to Description section, &quot;For Interferential Stimulation, please see policy DME0155 entitled Interferential Stimulation.&quot; No changes to the policy.</td>
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</table>
TENS (Transcutaneous Electrical Nerve Stimulator)

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.


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)
TENS (Transcutaneous Electrical Nerve Stimulator)

8/27/13  Reference added. (btw)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to guideline. (btw)


7/1/15  Reference added. (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)


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 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.