

# Protocol

## Transcutaneous Electrical Nerve Stimulation

(10109)

Medical Benefit		Effective Date: 10/01/14	Next Review Date: 09/15
Preauthorization	No	Review Dates: 09/09, 09/10, 09/11, 09/12, 09/13, 09/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

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).

#### Background

TENS has been used to treat chronic intractable pain, postsurgical pain, and pain associated with active or posttrauma 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. Percutaneous electrical nerve stimulation (PENS) 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 two 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 before 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.

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. (1)

#### Related Protocols

Temporomandibular Joint Dysfunction

Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

**Policy (Formerly Corporate Medical Guideline)**

A trial of transcutaneous electrical nerve stimulation (TENS) of at least 120 days may be considered **medically necessary** to establish efficacy for the management of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when the following conditions have been met:

- The pain is unresponsive to at least three months of conservative medical therapy; AND
- The trial is monitored by a physician.

Continued use of 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.

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**.

**Policy Guidelines**

Refractory chronic pain is defined in this Protocol as pain that causes significant disruption of function and has not responded to at least three months of conservative therapy, including nonsteroidal anti-inflammatory medications, ice, rest and/or physical therapy.

Documentation for the trial should include:

- 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., two 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.

**Medicare Advantage**

For Medicare Advantage the following applies in addition or in place of the above:

The use of TENS for acute post-op pain is **medically necessary** for relatively short periods usually 30 days or less (rental only).

### *Chronic Pain Other than Low Back Pain*

TENS is considered **medically necessary** for chronic, intractable pain other than chronic low back pain when all of the following criteria must be met:

- The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive):
  - headache
  - visceral abdominal pain
  - pelvic pain
  - temporomandibular joint (TMJ) pain
- The pain must have been present for at least three months
- Other appropriate treatment modalities must have been tried and failed

TENS therapy for chronic pain that does not meet these criteria is considered **not medically necessary**.

The use of TENS for chronic low back pain (CLBP) is only through an approved clinical trial (billed to original fee-for-service Medicare, not Medicare Advantage). This applies for CLBP that is:

- an episode of low back pain that has persisted for three months or longer; and
- is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.

A conductive garment is not medically necessary during a trial period unless there is a documented skin problem that makes it **medically necessary** to use one. But if after the trial it has been determined that the patient will need the TENS longer than 13 months, then a conductive garment is considered **medically necessary** if the following criteria are met:

- The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
- The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
- The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
- The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
- The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

---

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. 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](http://www.accessdata.fda.gov/cdrh_docs/reviews/K122566.pdf). Last accessed April, 2014.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). TENS or PENS in the treatment of chronic and postoperative pain. TEC Assessments 1996; Volume 11, Tab 21.
3. Carroll D, Moore RA, McQuay HJ et al. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev 2001; (3):CD003222.
4. Milne S, Welch V, Brosseau L et al. Transcutaneous electrical nerve stimulation (TENS) for chronic low back pain. Cochrane Database Syst Rev 2001; (2):CD003008.
5. Brosseau LU, Pelland LU, Casimiro LY et al. Electrical stimulation for the treatment of rheumatoid arthritis. Cochrane Database Syst Rev 2002; (2):CD003687.
6. Price CI, Pandyan AD. Electrical stimulation for preventing and treating post-stroke shoulder pain. Cochrane Database Syst Rev 2000; (4):CD001698.
7. Proctor ML, Smith CA, Farquhar CM et al. Transcutaneous electrical nerve stimulation and acupuncture for primary dysmenorrhoea. Cochrane Database Syst Rev 2002; (1):CD002123.
8. Osiri M, Welch V, Brosseau L et al. Transcutaneous electrical nerve stimulation for knee osteoarthritis. Cochrane Database Syst Rev 2000; (4):CD002823.
9. Brosseau L, Judd MG, Marchand S et al. Transcutaneous electrical nerve stimulation (TENS) for the treatment of rheumatoid arthritis in the hand. Cochrane Database Syst Rev 2003; (3):CD004377.
10. Cameron M, Lonergan E, Lee H. Transcutaneous electrical nerve stimulation (TENS) for dementia. Cochrane Database Syst Rev 2003; (3):CD004032.
11. Khadilkar A, Milne S, Brosseau L et al. Transcutaneous electrical nerve stimulation (TENS) for chronic low-back pain. Cochrane Database Syst Rev 2005; (3):CD003008.
12. Bronfort G, Nilsson N, Haas M et al. Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev 2004; (3):CD001878.
13. Kroeling P, Gross A, Houghton PE. Electrotherapy for neck disorders. Cochrane Database Syst Rev 2005; (2):CD004251.
14. Khadilkar A, Odebiyi DO, Brosseau L et al. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. Cochrane Database Syst Rev 2008; (4):CD003008.
15. Robb KA, Bennett MI, Johnson MI et al. Transcutaneous electric nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev 2008; (3):CD006276.
16. Nnoaham KE, Kumbang J. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev 2008; (3):CD003222.

17. Walsh DM, Howe TE, Johnson MI et al. Transcutaneous electrical nerve stimulation for acute pain. *Cochrane Database Syst Rev* 2009; (2):CD006142.
18. Dowswell T, Bedwell C, Lavender T et al. Transcutaneous electrical nerve stimulation (TENS) for pain relief in labour. *Cochrane Database Syst Rev* 2009; (2):CD007214.
19. Kroeling P, Gross A, Goldsmith CH et al. Electrotherapy for neck pain. *Cochrane Database Syst Rev* 2009; (4):CD004251.
20. Mulvey MR, Bagnall AM, Johnson MI et al. Transcutaneous electrical nerve stimulation (TENS) for phantom pain and stump pain following amputation in adults. *Cochrane Database Syst Rev* 2010; (5):CD007264.
21. Rutjes AW, Nuesch E, Sterchi R et al. Transcutaneous electrostimulation for osteoarthritis of the knee. *Cochrane Database Syst Rev* 2009; (4):CD002823.
22. Dubinsky RM, Miyasaki J. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2010; 74(2):173-6.
23. Keskin EA, Onur O, Keskin HL et al. Transcutaneous electrical nerve stimulation improves low back pain during pregnancy. *Gynecol Obstet Invest* 2012; 74(1):76-83.
24. Gossrau G, Wahner M, Kuschke M et al. Microcurrent transcutaneous electric nerve stimulation in painful diabetic neuropathy: a randomized placebo-controlled study. *Pain Med* 2011; 12(6):953-60.
25. Hurlow A, Bennett MI, Robb KA et al. Transcutaneous electric nerve stimulation (TENS) for cancer pain in adults. *Cochrane Database Syst Rev* 2012; 3:CD006276.
26. Dailey DL, Rakel BA, Vance CG et al. Transcutaneous electrical nerve stimulation reduces pain, fatigue and hyperalgesia while restoring central inhibition in primary fibromyalgia. *Pain* 2013; 154(11):2554-62.
27. Lauretti GR, Chubaci EF, Mattos AL. Efficacy of the use of two simultaneously TENS devices for fibromyalgia pain. *Rheumatol Int* 2013; 33(8):2117-22.
28. Schneider MP, Tellenbach M, Mordasini L et al. Refractory chronic pelvic pain syndrome in men: can transcutaneous electrical nerve stimulation help? *BJU Int* 2013; 112(2):E159-63.
29. Bjordal JM, Johnson MI, Lopes-Martins RA et al. Short-term efficacy of physical interventions in osteoarthritic knee pain. A systematic review and meta-analysis of randomised placebo-controlled trials. *BMC Musculoskelet Disord* 2007; 8:51.
30. Vance CG, Rakel BA, Blodgett NP et al. Effects of transcutaneous electrical nerve stimulation on pain, pain sensitivity, and function in people with knee osteoarthritis: a randomized controlled trial. *Phys Ther* 2012; 92(7):898-910.
31. Chen WL, Hsu WC, Lin YJ et al. Comparison of intra-articular hyaluronic acid injections with transcutaneous electric nerve stimulation for the management of knee osteoarthritis: a randomized controlled trial. *Arch Phys Med Rehabil* 2013; 94(8):1482-9.
32. Palmer S, Domaille M, Cramp F et al. Transcutaneous electrical nerve stimulation as an adjunct to education and exercise for knee osteoarthritis: a randomized controlled trial. *Arthritis Care Res (Hoboken)* 2014; 66(3):387-94.
33. Kroeling P, Gross A, Graham N et al. Electrotherapy for neck pain. *Cochrane Database Syst Rev* 2013; 8:CD004251.
34. Schoenen J, Vandersmissen B, Jeanette S et al. Migraine prevention with a supraorbital transcutaneous stimulator: a randomized controlled trial. *Neurology* 2013; 80(8):697-704.

35. Magis D, Sava S, d'Elia TS et al. Safety and patients' satisfaction of transcutaneous supraorbital neurostimulation (tSNS) with the Cefaly(R) device in headache treatment: a survey of 2,313 headache sufferers in the general population. *J Headache Pain* 2013; 14:95.
36. Johnson M, Martinson M. Efficacy of electrical nerve stimulation for chronic musculoskeletal pain: a meta-analysis of randomized controlled trials. *Pain* 2007; 130(1-2):157-65.
37. Deyo RA, Walsh NE, Martin DC et al. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med* 1990; 322(23):1627-34.
38. Machin D, Lewith GT, Wylson S. Pain measurement in randomized clinical trials: A comparison of two pain scales. *Clin J Pain* 1988; 4:161-8.
39. Oosterhof J, De Boo TM, Oostendorp RA et al. Outcome of transcutaneous electrical nerve stimulation in chronic pain: short-term results of a double-blind, randomised, placebo-controlled trial. *J Headache Pain* 2006; 7(4):196-205.
40. Oosterhof J, Samwel HJ, de Boo TM et al. Predicting outcome of TENS in chronic pain: a prospective, randomized, placebo controlled trial. *Pain* 2008; 136(1-2):11-20.
41. Oosterhof J, Wilder-Smith OH, de Boo T et al. The long-term outcome of transcutaneous electrical nerve stimulation in the treatment for patients with chronic pain: a randomized, placebo-controlled trial. *Pain Pract* 2012; 12(7):513-22.
42. Lang T, Barker R, Steinlechner B et al. TENS relieves acute posttraumatic hip pain during emergency transport. *J Trauma* 2007; 62(1):184-8; discussion 88.
43. DeSantana JM, Walsh DM, Vance C et al. Effectiveness of transcutaneous electrical nerve stimulation for treatment of hyperalgesia and pain. *Curr Rheumatol Rep* 2008; 10(6):492-9.
44. Silva MB, de Melo PR, de Oliveira NM et al. Analgesic effect of transcutaneous electrical nerve stimulation after laparoscopic cholecystectomy. *Am J Phys Med Rehabil* 2012; 91(8):652-7.
45. Bjersa K, Andersson T. High frequency TENS as a complement for pain relief in postoperative transition from epidural to general analgesia after pancreatic resection. *Complement Ther Clin Pract* 2014; 20(1):5-10.
46. Kayman-Kose S, Ario DT, Toktas H et al. Transcutaneous electrical nerve stimulation (TENS) for pain control after vaginal delivery and cesarean section. *J Matern Fetal Neonatal Med* 2014.
47. Simpson PM, Fouche PF, Thomas RE et al. Transcutaneous electrical nerve stimulation for relieving acute pain in the prehospital setting: a systematic review and meta-analysis of randomized-controlled trials. *Eur J Emerg Med* 2014; 21(1):10-7.
48. Chesterton LS, Lewis AM, Sim J et al. Transcutaneous electrical nerve stimulation as adjunct to primary care management for tennis elbow: pragmatic randomised controlled trial (TATE trial). *BMJ* 2013; 347:f5160.
49. Laufer Y, Elboim-Gabyzon M. Does sensory transcutaneous electrical stimulation enhance motor recovery following a stroke? A systematic review. *Neurorehabil Neural Repair* 2011; 25(9):799-809.
50. Tyson SF, Sadeghi-Demneh E, Nester CJ. The effects of transcutaneous electrical nerve stimulation on strength, proprioception, balance and mobility in people with stroke: a randomized controlled cross-over trial. *Clin Rehabil* 2013; 27(9):785-91.
51. Martelletti P, Jensen RH, Antal A et al. Neuromodulation of chronic headaches: position statement from the European Headache Federation. *J Headache Pain* 2013; 14(1):86.
52. McAlindon TE, Bannuru RR, Sullivan MC et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014; 22(3):363-88.

53. National Comprehensive Cancer Network NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) Adult Cancer Pain. 2013. Available online at: [http://www.nccn.org/professionals/physician\\_gls/pdf/pain.pdf](http://www.nccn.org/professionals/physician_gls/pdf/pain.pdf). Last accessed June, 2013.
54. National Cancer Institute. Pain (PDQ®). 2013. Available online at: <http://www.cancer.gov/cancertopics/pdq/supportivecare/pain/HealthProfessional/AllPages>. Last accessed June, 2013.
55. Bono CM, Ghiselli G, Gilbert TJ et al. North American Spine Society. An Evidence-based Clinical Guideline for the Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders. *Spine J* 2011; 11(1):64-72. Available online at: [http://www.spine.org/Documents/Cervical\\_Radiculopathy.pdf](http://www.spine.org/Documents/Cervical_Radiculopathy.pdf). Last accessed June, 2011.
56. American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine. Practice Guidelines for Chronic Pain Management: An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology* 2010; 112(4):810-33. Available online at: [http://journals.lww.com/anesthesiology/Fulltext/2010/04000/Practice\\_Guidelines\\_for\\_Chronic\\_Pain\\_Management\\_.13.aspx](http://journals.lww.com/anesthesiology/Fulltext/2010/04000/Practice_Guidelines_for_Chronic_Pain_Management_.13.aspx). Last accessed June, 2013.
57. American Society of Anesthesiologists. Practice guidelines for chronic pain management. A report by the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section. *Anesthesiology* 1997; 86(4):995-1004. Available online at: [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list\\_uids=9105246](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=9105246). Last accessed June, 2013.
58. National Institute for Health and Clinical Excellence (NICE). Low Back Pain. Early Management of Persistent Non-specific Low Back Pain. Clinical Guidance 88. 2009. Available online at: <http://www.nice.org.uk/nicemedia/live/11887/44334/44334.pdf>. Last accessed June, 2013.
59. National Institute for Health and Clinical Excellence (NICE). Osteoarthritis National Clinical Guideline for Care and Management in Adults. The National Collaborating Centre for Chronic Conditions and National Institute for Health and Clinical Excellence. Clinical Guidance 59. 2008. Available online at: <http://guidance.nice.org.uk/CG59/Guidance/pdf/English>. Last accessed June, 2013.
60. The National Collaborating Centre for Women's and Children's Health and the National Institute for Health and Clinical Excellence. Intrapartum Care of Healthy Women and Their Babies During Childbirth. Clinical Guidance 55. 2008. Available online at: <http://guidance.nice.org.uk/CG55/Guidance/pdf/English>. Last accessed June, 2013.
61. American Congress of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 51. Chronic Pelvic Pain. *Obstet Gynecol* 2004; 103(3):589-605.
62. Chou R, Qaseem A, Snow V et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med* 2007; 147(7):478-91.
63. Cruccu G, Aziz TZ, Garcia-Larrea L et al. EFNS guidelines on neurostimulation therapy for neuropathic pain. *Eur J Neurol* 2007; 14(9):952-70.
64. Ferrell B, Casarett D, Epplin J et al. The AGS Guideline on the Management of Persistent Pain in Older Persons. *J Am Geriatr Soc* 2002; 50(6 Suppl):S205-24.



65. Centers for Medicare and Medicaid. National Coverage Determination for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13). 1995. Available online at: <http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=280.13&bc=gAAAAAAAAAAAA&>. Last accessed June, 2013.
66. Centers for Medicare and Medicaid. National Coverage Determination for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) 2006. Available online at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=63&ncdver=2&DocID=160.7.1&bc=gAAAAAgAAAA&>. Last accessed June, 2013.
67. Centers for Medicare and Medicaid. National Coverage Determination for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13) 1988. Available online at: <http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=160.13&bc=gAAAAAAAAAAAA&>. Last accessed June, 2013.
68. Centers for Medicare and Medicaid. National Coverage Determination for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2) 1995. Available online at: <http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=10.2&bc=gAAAAAAAAAAAA&>. Last accessed June, 2013.
69. Centers for Medicare and Medicaid. Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N) 2012. Available online at: <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=256>. Last accessed June, 2013.
70. Medicare Contractor NHIC Local Coverage Determination (LCD): Transcutaneous Electrical Nerve Stimulators (TENS) (L11506), Revision Effective Date for services performed on or after 10/01/2013.