

FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

Effective Date: April 15, 2018

Related Policies:

- 1.01.24 Interferential Current Stimulation
- 2.01.21 Temporomandibular Joint Dysfunction
- 7.01.29 Percutaneous Electrical Nerve Stimulation or Percutaneous Neuromodulation Therapy

Transcutaneous Electrical Nerve Stimulation

Description

Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin at the site of pain. In addition to more traditional settings such as a physician's office or an outpatient clinic, TENS can be self-administered in a patient's home.

FDA 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 been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Marketing clearance via the 510(k) process does not require data on clinical efficacy; as a result, these cleared devices are considered substantially equivalent to predicate devices marketed in interstate commerce before May 1976, the enactment date of the Medical Device Amendments. The cleared devices are also equivalent to devices that have been reclassified and do not require a premarket approval application. FDA product code: GZJ.

In 2014, the Cefaly® (STX-Med, Herstal, Belgium), which is a TENS device, was granted a de novo 510(k) classification by FDA for the prophylactic treatment of migraine in patients 18 years of age or older.¹ FDA product code: PCC.

POLICY STATEMENT

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 (eg, 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 TENS may be considered **medically necessary** for treatment of refractory chronic pain (eg, chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when the following conditions have been met:

FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

- Efficacy has been demonstrated in an initial therapeutic trial (see Policy Guidelines section); AND
- Compliance has been demonstrated in the therapeutic trial with the device used on a regular basis (eg, daily or near daily use) throughout the trial period.

TENS is considered **investigational** for the management of acute pain (eg, 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

For the purposes of these policy guidelines, refractory chronic pain is defined 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:

- 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 transcutaneous electrical nerve stimulation (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 (eg, 2-point or 30% improvement in visual analog scale);
- 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have chronic pain (eg, 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

FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

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, 2 large RCTs found no benefit of TENS compared with sham TENS. For the prevention of migraine headaches, a 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. 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

European Headache Federation

The European Headache Federation (2013), citing concerns about an ineffective sham procedure for transcutaneous electrical nerve stimulation (TENS) in headache methodology studies and the overall limited level of evidence, recommended that there was insufficient evidence for the use of TENS in headache prophylaxis and to abort an acute headache.⁶⁰

Osteoarthritis Research Society International

Guidelines from the Osteoarthritis Research Society International (2014) recommended that TENS was not appropriate for use in patients with multijoint osteoarthritis; moreover, the guidelines suggested that TENS has an uncertain value for the treatment of knee-only osteoarthritis pain.⁶¹

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on adult cancer pain (v.2.2017) indicate that nonpharmacologic interventions, including TENS, may be considered in conjunction with pharmacologic interventions as needed (category 2A).⁶²

National Cancer Institute

National Cancer Institute (2014) guidelines on pain stated that noninvasive physical and psychosocial modalities can be used concurrently with drugs and other interventions to manage pain during all phases of cancer treatment.⁶³ Moreover, the Institute suggested that patients with mild-to-moderate cancer pain may benefit from a trial of TENS to see if it is effective in reducing pain. TENS is a low-risk intervention.

North American Spine Society

The North American Spine Society (2011) clinical guidelines on the diagnosis and treatment of cervical radiculopathy from degenerative disorders discussed the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and TENS in the treatment of cervical radiculopathy from degenerative disorders.⁶⁴ A consensus statement from the Society recommended that ozone injections, cervical halter traction, and combinations of medications, physical therapy, injections, and traction have been associated with improvements in patient-reported pain in uncontrolled case series. Such modalities may be considered, recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated.

FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

American Academy of Neurology

In 2010, the American Academy of Neurology published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders.²⁴ The Academy did not recommend TENS for the treatment of chronic low back pain due to lack of proven efficacy (level A, established evidence from 2 class I studies), and that TENS should be considered for the treatment of painful diabetic neuropathy (level B, probably effective, based on 2 class II studies).

American Society of Anesthesiologists et al

The 2010 practice guidelines from the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine recommended that TENS be used as part of a multimodal approach to management for patients with chronic back pain and may be used for other pain conditions (eg, neck and phantom limb pain).⁶⁵ The American Society of Anesthesiologists' 1997 guidelines on chronic pain management recommended that an office or home trial of TENS should be considered as an early management option or as an adjunctive therapy because of its low complexity and low risk.⁶⁶

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) 2009 guidance on low back pain indicated that, despite the long history of use of TENS for back pain, the quality of research studies is poor.⁶⁷ This guidance did not recommend TENS as a treatment due to lack of evidence of efficacy.

NICE 2008 guidance on osteoarthritis care and management in adults indicated that:

"[T]here is evidence that TENS is clinically beneficial for pain relief and reduction of stiffness in knee osteoarthritis, especially in the short term. However, this was not shown in a community setting. There is no evidence that efficacy trails off over time, or that periodic use for exacerbations is helpful.... People with osteoarthritis should be encouraged to experiment with intensities and duration of application if the desired relief of symptoms is not initially achieved. This enables patients' control of their symptoms as part of a self-management approach. A further follow-up visit is essential in allowing the health professional to check patients' usage of TENS and problem solve. No adverse events or toxicity have been reported with TENS."⁶⁸

NICE 2008 guidance on intrapartum care indicated there is high-level evidence that TENS was not an effective analgesic in established labor, and there was no high-level evidence on the analgesic effect of TENS in the latent phase of labor.⁶⁹ NICE recommended that TENS not be offered to women in established labor.

American Congress of Obstetricians and Gynecologists

American Congress of Obstetricians and Gynecologists (ACOG) 2007 guidelines for women's health care state that methods of neurostimulation, such as TENS, acupuncture, and massage, were based on the gate theory of pain control.⁷⁰ These treatments can be useful for pain control, particularly when the pain is severe. The guidelines recommended that because different methods of treatment work by different mechanisms (eg, relaxation techniques, TENS, physical therapy, vocational rehabilitation, biofeedback), the use of multiple treatment modalities in synergy should be considered.

The 2004 ACOG guidelines on chronic pelvic pain found that clinical trials evaluating the efficacy of acupuncture, acupressure, and TENS therapies had been performed only for primary dysmenorrhea, not for nonmenstrual pelvic pain.⁷¹ The guidelines recommended that acupuncture, acupressure, and TENS therapies be considered to decrease the pain of primary dysmenorrhea.

The 2017 ACOG guidelines on labor and delivery found that TENS may "help women cope with labor more than directly affect pain scores."⁷²

FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

American College of Physicians

The American College of Physicians published guidelines on noninvasive therapies for acute and low back pain in 2017.^{73,74} No recommendations for TENS were made; the panel concluded that “evidence was insufficient to determine the effectiveness” of TENS and that there was no long-range data.

European Federation of Neurological Societies

The European Federation of Neurological Societies (2007) published guidelines on neurostimulation for neuropathic pain.⁷⁵ The guidelines task force did not make conclusive recommendations, with only approximately 200 patients with different diseases, based on studies using different parameters and comparators, and having variable results. The task force concluded that standard high-frequency TENS is possibly (level C) better than placebo and probably (level B) worse than acupuncture-like or any other kind of electrical stimulation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently have the following national coverage decisions on TENS.⁷⁶⁻⁸⁰ The different coverage decisions address the use of TENS in the treatment of chronic intractable pain, noncoverage of TENS for chronic low back pain except to conduct research for said indication, and coverage for acute postoperative pain.

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FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

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FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

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FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

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FEP 1.01.09 Transcutaneous Electrical Nerve Stimulation

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POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
December 2013	Update Policy	Policy updated with literature review, references 22, 24, 26, 32 35, 36 & 54 added. Policy statements are unchanged.
June 2014	Update Policy	Policy updated with literature review; References 1, 26-28, 3135, 45-48, 50-52 added; last policy statement revised to specifically list use of TENS in prevention of migraine headaches as not medically necessary.
June 2015	Update Policy	Policy updated with literature review. References 33, 43, and 45-46 added, and references 55-56 updated; policy statements unchanged.
June 2016	Update Policy	Policy updated with literature review through October 12, 2015 references 33-34, 50, and 52 added. Policy statements unchanged.
March 2018	Update Policy	Policy updated with literature review through September 12, 2017; references 33, 39-40, 49, and 55 added. Policy statements unchanged except "not medically necessary" corrected to "investigational" due to 510k status.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.