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Medical Benefit		Effective Date: 01/01/16	Next Review Date: 09/19
Preauthorization	No	Review Dates: 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions)	Interventions of interest are: • Transcutaneous electrical nerve stimulation	Comparators of interest are: • Physical therapy • Pharmacotherapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use
Individuals: • With acute pain (e.g., surgical, musculoskeletal, labor, and mixed pain conditions)	Interventions of interest are: • Transcutaneous electrical nerve stimulation	Comparators of interest are: • Pharmacotherapy	Relevant outcomes include: • Symptoms • Medication use

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.

SUMMARY OF EVIDENCE

For individuals who have chronic pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions) who receive TENS, the evidence 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 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 indica-

tions. 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, two 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.

POLICY

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

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 three months of conservative therapy, including non-steroidal 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);
- 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 policy statements:

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 are 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**.

TENS for chronic low back pain is considered **not medically necessary**.

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, 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 to treat chronic intractable pain.

BACKGROUND

TENS has been used to treat chronic intractable pain, postsurgical 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 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 (see the Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy Protocol) 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 the stimulation 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 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.

RELATED PROTOCOLS

Percutaneous Electrical Nerve Stimulation or Percutaneous Neuromodulation Therapy

Temporomandibular Joint Dysfunction

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.

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