MEDICAL POLICY – 7.01.29
Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Effective Date: June 1, 2017
Last Revised: May 2, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.507 Electrical Stimulation Devices
8.01.58 Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Using mild electrical current is one way to treat nerve pain. It’s believed that the electrical signals interfere with the way nerves relay information about pain to the brain. TENS, which uses electricity transferred through the skin, has been in use for decades and is well proven. Newer ways of delivering small electrical impulses are being studied. Percutaneous electrical nerve stimulation (PENS) uses small needles placed just below the skin, with electricity delivered by a battery-powered stimulator. In percutaneous neuromodulation therapy (PNT), fine needle electrodes are placed in deep tissues. Because more high-quality studies are needed to determine if PENS and PNT are effective, they are both still considered unproven.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
**Procedure**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Percutaneous electrical neurostimulation or neuromodulation</td>
<td>Percutaneous electrical neurostimulation or neuromodulation is considered investigational.</td>
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</table>

**Guidelines**

Percutaneous electrical neurostimulation (PENS) and percutaneous neuromodulation (PNT) use needle and wire electrodes that are inserted into the skin above a nerve, rather than having electrodes implanted on the skin.

The stimulation devices used in PENS and PNT are also not implanted.

**Coding**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
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**Related Information**

N/A

**Evidence Review**

**Description**

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. PENS is performed with needle electrodes while PNT uses very fine needle-like
electrode arrays placed in close proximity to the painful area to stimulate peripheral sensory nerves in the soft tissue.

Background

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) have been evaluated for the treatment of a variety of chronic musculoskeletal or neuropathic pain conditions including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia. Chronic pain presents a substantial burden to patients, adversely affecting function and quality of life. These chronic pain conditions have typically failed other treatments, and the goal of treatment with PENS and PNT is to relieve unremitting pain.

Percutaneous electrical nerve stimulation (PENS) is similar in concept to transcutaneous electrical nerve stimulation or TENS (see Related Policies) but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area and are then stimulated. PENS is generally reserved for patients who fail to get pain relief from TENS. PENS is also different from acupuncture with electrical stimulation (see Related Policies). In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. In PENS, the needles are placed close to the nerves serving the painful area rather than depending on the theories of energy flow that guide placement of needles for acupuncture.

Percutaneous neuromodulation therapy (PNT) is a variant of PENS in which fine filament electrode arrays are placed near the area that is causing pain. Some use the terms PENS and PNT interchangeably. It is proposed that PNT inhibits pain transmission by creating an electrical field that hyperpolarizes C-fibers, thus preventing action potential propagation along the pain pathway.

Summary of Evidence

For individuals who have chronic pain conditions (eg, back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) and receive percutaneous electrical nerve stimulation (PENS), the evidence includes primarily small controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In the highest quality trial of PENS conducted to date, no difference in outcomes was found between the active (30 minutes of stimulation with 10 needles) and the sham (5 minutes of stimulation with 2 needles) treatments.
Smaller trials, which have reported positive results, are limited by unclear blinding and short-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) who receive percutaneous neuromodulation therapy, the evidence only consists of 1 randomized controlled trial. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The single trial is limited by lack of investigator blinding, unclear participant blinding, and short-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 5 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. The input was mixed regarding whether PENS and PNT should be considered investigational or medically necessary.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

The U.K.’s NICE (National Institute for Health and Care Excellence) published guidance on PENS in 2013.\textsuperscript{15} NICE concluded that the current evidence on the safety of PENS for refractory neuropathic pain raises no major safety concerns, that there is evidence of efficacy in the short term and that this procedure may be used with normal arrangements for clinical governance, consent and audit.
American Academy of Neurology et al.

The American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation published an evidence-based guideline on the treatment of painful diabetic neuropathy in 2011. The guideline concluded that, based on a Class I study, electrical stimulation is probably effective in lessening the pain of diabetic neuropathy and improving quality of life. It was recommended that PENS be considered for the treatment of painful diabetic neuropathy (level B).

American Society of Anesthesiologists et al.

The 2010 practice guidelines for chronic pain management from the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine state that subcutaneous peripheral nerve stimulation may be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies (Category B2 evidence, observational studies).

American College of Physicians and American Pain Society

Joint clinical practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicate that there is uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture. The guidelines conclude that PENS is not widely available. (The guidelines also conclude that TENS has not been proven effective for chronic low back pain.)

Medicare National Coverage

The Centers for Medicare and Medicaid Services (CMS) currently has the following national coverage policy on PENS:

“Electrical nerve stimulation is an accepted modality for assessing a patient’s suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:
B. Percutaneous Electrical Nerve Stimulation (PENS).--This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services that are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §280.13 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

Regulatory Status

- Percutaneous Neuromodulation Therapy™ (Vertis Neurosciences) received approval to market by FDA through the 510(k) process in 2002. The labeled indication reads as follows, “Percutaneous neuromodulation therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain.”
The Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave) received 510(k) approval in 2006, listing the Vertis Neuromodulation system and a Biowave TENS unit as predicate devices. The Deepwave system includes a sterile single-use percutaneous electrode array that contains 1,014 microneedles in a 1.5-inch diameter area. The needles are 736 μm (0.736 mm) in length; the patch is reported to feel like sandpaper or Velcro.

FDA product code: NHI.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcutaneous electric nerve stimulation (TENS) or percutaneous electric nerve stimulation (PENS) in the treatment of chronic and postoperative pain TEC Assessments. 1996;Volume 11:Tab 21.


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>03/13/12</td>
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<td>10/26/12</td>
<td>Replace Policy. Rationale section revised based on literature review through June 2012. References 13 and 16 added; other references renumbered or removed. Policy statement unchanged.</td>
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<td>11/20/12</td>
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<td>02/14/13</td>
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<td>09/11/13</td>
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<td>09/27/13</td>
<td>Replace policy. Policy updated with literature review through June 4, 2013; reference 17 added; policy statement unchanged.</td>
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<td>03/21/14</td>
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<tr>
<td>06/01/17</td>
<td>Annual Review, approved May 2, 2017. Policy moved to new format. Policy updated with literature review through January 26, 2017; some references removed. Minor edits to the Policy section; policy statement otherwise unchanged.</td>
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