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

SELECT A HYPERLINK BELOW TO BE DIRECTED TO THAT SECTION.

**POLICY CRITERIA | CODING | RELATED INFORMATION**

**EVIDENCE REVIEW | REFERENCES | HISTORY**

∞ Clicking this icon returns you to the hyperlinks menu above.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous electrical neurostimulation or percutaneous neuromodulation</td>
<td>Percutaneous electrical neurostimulation or percutaneous neuromodulation therapy is considered investigational.</td>
</tr>
</tbody>
</table>

Guidelines

Percutaneous electrical neurostimulation (PENS) and percutaneous neuromodulation therapy (PNT) use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review
Description

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

Background

Chronic Pain

A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, presents a substantial burden to patients, adversely affecting function and quality of life.

Treatment

These chronic pain conditions have typically failed other treatments, and percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) have been evaluated as treatments to relieve unremitting pain.

PENS is similar in concept to transcutaneous electrical nerve stimulation (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 transcutaneous electrical nerve stimulation. PENS is also distinguished from acupuncture with electrical stimulation. 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 location of stimulation is determined by proximity to the pain.

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) who receive 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 (eg, knee osteoarthritis) who receive percutaneous neuromodulation therapy, the evidence consists of a 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
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<tr>
<td>NCT04243915</td>
<td>Effectiveness of Percutaneous Neuromuscular ElectricalStimulation on Lumbar Multifidus in Combination With a Protocol of Motor Control Exercises in Patients With Chronic Low Back Pain</td>
<td>64</td>
<td>Apr 2021</td>
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<tr>
<td></td>
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<td></td>
<td></td>
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<tr>
<td><strong>Unpublished</strong></td>
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</tr>
<tr>
<td>NCT03331055</td>
<td>Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for Pain in Patients With Pancreatic Cancer</td>
<td>36</td>
<td>Aug 2019</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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</tr>
<tr>
<td>NCT03338543</td>
<td>Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for Pain in Patients With Liver Cancer</td>
<td>36</td>
<td>Sep 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, 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 five physician specialty societies and two academic medical centers while this policy was under review in 2011. Input was mixed on whether percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy should be considered investigational or medically necessary.

**Practice Guidelines and Position Statements**

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2013) published guidance on percutaneous electrical nerve stimulation (PENS). It concluded that the “Current evidence on the safety of percutaneous electrical nerve stimulation (PENS) for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term.”

**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 reaffirmed 2011 evidence-based guidelines on the treatment of painful diabetic neuropathy in 2016. The guidelines 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 and 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 and the American Society of Regional Anesthesia and Pain Medicine indicated that subcutaneous peripheral nerve stimulation might 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).16

**American College of Physicians and American Pain Society**

Joint practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicated uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture.17 The guidelines concluded that PENS is not widely available. (The guidelines also concluded that transcutaneous electrical nerve stimulation 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 PENS18:

> 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)

The 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.

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.

Regulatory Status

- In 2002, the Percutaneous Neuromodulation Therapy™ (Vertis Neuroscience) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The labeled indication is: “... 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.”

- In 2006, the Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to the Vertis neuromodulation system and a Biowave neuromodulation therapy unit. 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.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>03/13/12</td>
<td>New policy. Add to Surgery section. Removed from 1.01.507.</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>Update Related Policies. Add 8.01.58.</td>
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<td>09/11/13</td>
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<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>
<td>Update Related Policies. Delete 7.01.106 and replace with 7.01.553.</td>
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<td>09/23/14</td>
<td>Annual Review. Policy updated with literature review through June 6, 2014; policy statement unchanged.</td>
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<td>04/17/15</td>
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<td>Annual Review, approved August 9, 2016. Policy updated with literature review; no references added. Policy statement unchanged.</td>
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<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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<td>09/01/19</td>
<td>Annual Review, approved August 6, 2019. Policy updated with literature review through April 2018; no references added. Policy statement unchanged.</td>
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