FEP 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Effective Date: July 15, 2017

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.

FDA 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: “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.” 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 1014 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.

POLICY STATEMENT
Percutaneous electrical neurostimulation or percutaneous neuromodulation therapy is considered not medically necessary.

BENEFIT APPLICATION
Services, drugs, or supplies that are not medically necessary are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence
For individuals who have chronic pain conditions (eg, back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) who receive percutaneous electrical nerve stimulation (PENS), the evidence includes primarily small controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life,
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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, back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) who receive percutaneous neuromodulation therapy, the evidence 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
National Institute for Health and Care Excellence

The U.K.’s National Institute for Health and Care Excellence (NICE) published guidance on percutaneous electrical nerve stimulation (PENS) in 2013. NICE 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. Therefore the procedure may be used with normal arrangements for clinical governance, consent and audit."

U.S. Preventive Services Task Force Recommendations

Not applicable.

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….

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 (transcutaneous electrical nerve stimulation] 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.)”.

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.
17. Practice guidelines for chronic pain management: an updated report by the American Society...
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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>Revise Policy</td>
<td>Policy updated with literature review, references 12, 13, 16 &amp; 17 added and references re-ordered. No change to policy statement or summary.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through January 26, 2017; some references removed. Minor edits to the Policy section; policy statement unchanged.</td>
</tr>
<tr>
<td>June 2017</td>
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