

Protocol

Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

(70129)

Medical Benefit		Effective Date: 10/01/09	Next Review Date: 03/21
Preauthorization	Yes	Review Dates: 05/09, 03/10, 03/11, 03/12, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

Preauthorization is required for Medicare Advantage.

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: <ul style="list-style-type: none">• With chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia)	Interventions of interest are: <ul style="list-style-type: none">• Percutaneous electrical nerve stimulation	Comparators of interest are: <ul style="list-style-type: none">• Continued medical management	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Quality of life• Medication use
Individuals: <ul style="list-style-type: none">• With chronic pain conditions (e.g., knee osteoarthritis)	Interventions of interest are: <ul style="list-style-type: none">• Percutaneous neuro-modulation therapy	Comparators of interest are: <ul style="list-style-type: none">• Continued medical management	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Quality of life• Medication use

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.

SUMMARY OF EVIDENCE

For individuals who have chronic pain conditions (e.g., 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 ten needles) and the sham (five minutes of stimulation with two 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., knee osteoarthritis) who receive percutaneous neuro-modulation 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.

POLICY

Percutaneous electrical neurostimulation or percutaneous neuromodulation therapy is considered **investigational**.

MEDICARE ADVANTAGE

Percutaneous electrical nerve stimulation is **medically necessary** when performed by a physician or incident to physician's service, to determine if pain is effectively controlled by percutaneous stimulation, therefore warranting implantation of electrodes.

MEDICARE ADVANTAGE POLICY GUIDELINES

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 one month. In a few cases, this determination may take longer to make.

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 the Transcutaneous Electrical Nerve Stimulation Protocol) 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 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.

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 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.

RELATED PROTOCOLS

Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Surgical Treatment of Bilateral Gynecomastia

Temporomandibular Joint Dysfunction

Transcutaneous Electrical Nerve Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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.

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 post-operative pain TEC Assessments. 1996;Volume 11:Tab 21.
2. Weiner DK, Perera S, Rudy TE, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. *Pain*. Nov 30 2008;140(2): 344-357. PMID 18930352
3. Weiner DK, Rudy TE, Glick RM, et al. Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults. *J Am Geriatr Soc*. May 2003;51(5):599-608. PMID 12752833
4. Yokoyama M, Sun X, Oku S, et al. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. *Anesth Analg*. Jun 2004;98(6):1552-1556, table of contents. PMID 15155304

