

Protocol

Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

(70129)

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

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, knee osteoarthritis)	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., back, neck, headache, neuropathy, hyperalgesia, knee osteoarthritis)	Interventions of interest are: <ul style="list-style-type: none">• Percutaneous neuromodulation 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 (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.

Summary of Evidence

For individuals who have chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) 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 (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., back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) who receive PNT, the evidence consists of one 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

PENS and 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.

PENS is similar in concept to transcutaneous electrical nerve stimulation (TENS; 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 TENS. 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: "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 market-

ing 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

Temporomandibular Joint Dysfunction

Transcutaneous Electrical Nerve Stimulation

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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