Medical Coverage Policy | Percutaneous Electrical Nerve Stimulation and Percutaneous Neruomodulation Therapy

EFFECTIVE DATE: 04|18|2017
POLICY LAST UPDATED: 04|18|2017

OVERVIEW

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 for the treatment of chronic pain conditions.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Product

Percutaneous electrical neurostimulation (PEN) or percutaneous neuromodulation therapy (PNT) for the treatment of chronic pain conditions is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

MEDICAL CRITERIA

Not applicable

COVERAGE

BlueCHiP for Medicare and Commercial Products

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) 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 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.

For individuals who have chronic pain conditions (eg, 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 (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 PNT, 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.

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.

CODING

BlueCHiP for Medicare and Commercial Products

There is not a specific code for PENS or PNT, use the unlisted code below following the unlisted process
64999: Unlisted procedure, nervous system

RELATED POLICIES

Transcutaneous Electrical Nerve Stimulation
Interferential Current Stiumlation
Peripheral Subcutaneous Field Stimulation
Cranial Electrotherapy Stimulation and Auricular Electrostimulation

PUBLISHED

Provider Update, June 2017

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