Corporate Medical Policy

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy

File Name:	percutaneous_electrical_nerve_stimulation_(pens)_or_neuromodulation_therapy
Origination:	3/1980
Last CAP Review:	10/2020
Next CAP Review:	10/2021
Last Review:	10/2020

Description of Procedure or Service

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

Background

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (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 TENS 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 rather than the theories of energy flow that guide placement of stimulation for acupuncture.

Percutaneous neuromodulation therapy 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.

Regulatory Status

Percutaneous Neuromodulation Therapy™ (Vertis Neurosciences) received approval to market by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2002. The labeled indication reads as follows, “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.” The Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave) received 510(k) approval in 2006, listing the Vertis Neuromodulation system and a Biowave neuromodulation therapy unit as predicate devices. 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 microns (0.736 millimeters) in length; the patch is reported to feel like sandpaper or Velcro.

Related Policies

Transcutaneous Electrical Nerve Stimulation (TENS)
Interferential Stimulation
Neurostimulation, Electrical
Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician***.

Policy

Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy is covered

Not applicable.

When Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy is not covered

Percutaneous electrical neurostimulation and percutaneous neuromodulation therapy are considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

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 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *There are no specific CPT or HCPCS codes for this service*

Providers may submit claims for these services using the unlisted code 64999. Providers should not be using 64553-64565, or 64590 to bill this service as these codes are not appropriate.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Percutaneous Electrical Nerve Stimulation

BCBSA Medical Policy Reference Manual - 11/1996

Medical Policy Advisory Group Review - 3/1999

Specialty Matched Consultant Advisory Panel - 11/1999

Medical Policy Advisory Group - 12/1999

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 1/8/2009

Senior Medical Director Review - 3/2009

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 2/11/2010

Chou R, Qaseem A, Snow V et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007; 147(7):478-91.

Specialty Matched Consultant Advisory Panel – 11/2010

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 8/11/2011

Specialty Matched Consultant Advisory Panel – 11/2011

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 8/9/2012

Senior Medical Director – 10/2012

Specialty Matched Consultant Advisory Panel – 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 7/11/2013

Senior Medical Director – 8/2013

Specialty Matched Consultant Advisory Panel – 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 7/10/2014

Specialty Matched Consultant Advisory Panel – 10/2014

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 7/9/2015

Specialty Matched Consultant Advisory Panel – 10/2015

Specialty Matched Consultant Advisory Panel – 10/2016

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 3/9/2017

Specialty Matched Consultant Advisory Panel – 10/2017

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 6/14/2018

Specialty Matched Consultant Advisory Panel – 10/2018

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 6/13/2019

Specialty Matched Consultant Advisory Panel – 10/2019

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.29. 6/18/2020

Specialty Matched Consultant Advisory Panel – 10/2020

Policy Implementation/Update Information

3/80 Original Policy: Generally accepted medical practice for chronic intractable pain.

6/83 Reaffirmed

Percutaneous Electrical Nerve Stimulation

8/88 Reviewed: Eligible for coverage for patients in whom failure of TENS is thought to be due to physical barrier to electrical stimulation.

2/97 Reaffirmed. National Association reviewed 11/30/96.

3/99 Reviewed by MPAG. Reaffirmed.

7/99 Reformatted, Medical Term Definitions added.

12/99 Reaffirmed, Medical Policy Advisory Group.

4/01 System changes.

7/1/01 Policy archived.

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy

4/13/09 Policy from archive. Original name of policy, "Percutaneous Electrical Nerve Stimulation" has been changed to "Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy". Senior Medical Director Review 3/16/09. "Description" section updated. "Policy" statement indicates; "BCBSNC will not provide coverage for Percutaneous Electrical Nerve Stimulation (PENS) or Percutaneous Neuromodulation Therapy (PNT) because they are considered investigational." References added. Notification date 4/13/09. Effective date of policy 7/20/09.

6/22/10 Policy Number(s) removed (amw)

12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/10. "Description" section revised. Reworded "Policy" statement, no change to intent. Added comment to "Billing/Coding" section to indicate; "***Providers should not be using 64553-64565, or 64590 to bill this service as these codes are not appropriate."*** References added. (btw)

10/11/11 Reference added. (btw)

1/10/12 Specialty Matched Consultant Advisory Panel review 11/30/11. No change to policy intent. (btw)

10/30/12 Description section revised. Medical Director review 10/14/2012. Specialty Matched Consultant Advisory Panel review 10/17/12. Reference added. (btw)

9/10/13 Description and Policy Guidelines sections updated. Senior Medical Director review 8/29/2013. Reference added. (btw)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to policy. (btw)

9/30/14 Reference added. (sk)

11/25/14 Specialty Matched Consultant Advisory Panel review 10/28/2014. No change to policy. (sk)

9/1/15 Reference added. (sk)

11/24/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. (sk)

11/22/16 Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)

5/26/17 Reference added. Description updated. Policy Guidelines updated. (sk)

11/10/17 Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)

11/9/18 Reference added. Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)

8/27/19 Reference added. (sk)

11/26/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)

11/10/20 Reference added. Specialty Matched Consultant Advisory Panel review 10/21/2020. (sk)