

Corporate Medical Policy

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS)

File Name: percutaneous_electrical_nerve_stimulation_(pens)_or_neuromodulation_therapy_and_percutaneous_electrical_nerve_field_stimulation_penfs
Origination: 3/1980
Last CAP Review: 10/2020
Next CAP Review: 10/2021
Last Review: 6/2021

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. Percutaneous electrical nerve field stimulation (PENFS) differs from PENS in that with PENFS, a “field” of pain is targeted, instead of targeting a specific nerve.

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.

IB-stim, (formally Neuro-Stim), is an auricular PENFS device for use as adjunctive treatment of functional abdominal pain in adolescents. IB-stim delivers alternating frequencies of stimulation to the branches of cranial nerves that innervate the external ear. The suggested mechanism to address abdominal pain is modulation of the response of the amygdala and spinal neurons through the peripheral branches of cranial nerves V, VII, IX and X, altering visceral hypersensitivity. The device consists of a battery-powered, electrical generator that is secured behind the ear and connected by wires to four needle electrodes implanted beneath the skin near neurovascular bundles in the ear.

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The device is single-use and intended to be worn 120 hours a week and then discarded, with a one month treatment course consisting of four devices, one device per week.

Functional abdominal pain disorders (FAPDs) are the most common cause of chronic abdominal pain in children and adolescents, and involve a complex interplay among regulation of the enteric and central nervous systems. FAPD includes several pain-predominant functional gastrointestinal (GI) disorders: functional dyspepsia, irritable bowel syndrome, abdominal migraine and FAP-not otherwise specified. Symptoms associated with FAPD may include visceral hyperalgesia and a reduced threshold for pain, and may adversely affect mental health.

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.

IB-stim (Innovative Health Solutions) received approval on June 7, 2019 for abdominal pain in adolescents with irritable bowel syndrome.

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.

Percutaneous Electrical Nerve Field Stimulation (PENFS), including IB-stim, is 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.

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

Not applicable.

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

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

Percutaneous electrical nerve field stimulation is considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

Evidence Summaries

PENS/PNT

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.

PENFS

For individuals who have abdominal pain-related functional GI disorders, the evidence consists of one randomized, double-blind, sham-controlled trial and a subsequent subset analysis of the trial participants with irritable bowel syndrome. Relevant outcomes include symptoms, quality of life and medication use.

The trial (Kovacic et al., 2017) randomized 115 children with abdominal pain-related functional GI disorders to an active device (n=57) or sham (inactive device) (n=47). This was a modified intent to treat (ITT) analysis, after 11 patients were excluded for discontinued treatment and those excluded after randomization for organic disease. Participants were between the ages of 11 and 18 years, with any of the abdominal pain-related functional GI disorders and an average abdominal pain intensity of 3 or higher (on a 1-10 scale). Participants were 91% girls and 89% Caucasian. Approximately half had irritable bowel syndrome and the remainder functional dyspepsia,

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abdominal migraine or functional abdominal pain syndrome. The number of medications previously trialed ranged from 2-11.

Primary efficacy endpoint was change in abdominal pain scores, measuring improvement in worst abdominal pain and composite pain using the Pain Frequency-Severity-Duration (PFSD) scale. The PFSD scale incorporates multiple aspects of pain and was modified for this trial to rate weekly pain to include ratings of usual and worst pain and number of days in pain. A composite score was derived, with a highest possible score of 70. Median PFSD composite scores decreased after 3 weeks in the PENFS group compared with sham from 24.5 to 8.4 and 22.8 to 15.2 ($p < .0001$), respectively. These effects were sustained at extended follow-up in the PENFS group: median 24.4 at baseline to 12 at follow-up compared with 22.8 at baseline to 16.8 at follow-up in the sham group. Patients in the PENFS group had greater reduction in worst pain compared with sham at 3 weeks with median score of 5.0 vs 7.0, and effects were sustained for an extended period (median follow-up 9.2 weeks) in the PENFS group median 8.0 at baseline to 6.0 at follow-up vs sham 7.5 at baseline to 7.0 at follow-up ($p < .0001$). There was no significant difference between the two groups for secondary outcomes (global wellbeing, functional disability and anxiety).

Limitations of the study include a homogenous group of female, white participants, and inclusion of multiple subtypes of functional abdominal pain disorders. The study group participants had tried a wide range of number and classes of medications prior to study enrollment. The follow-up period was short (8-12 weeks) and study design used a modified ITT analysis. And while certain outcome scores were of statistical significance between groups, the clinical significance of these differences is unclear.

In summary, for the use of IB-stim in adolescent functional abdominal pain, additional study is needed to understand the efficacy of this device and its role in the overall treatment of these disorders. Future studies should aim to define the optimal target population, duration of therapy, and in what clinical setting (line of therapy) this device would be used. 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

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS)

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

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS)

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

Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS)

Kovacic K, Hainsworth K, Sood M, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol.* 2017 Oct;2(10):727-737.

Krasaelap A, Sood MR, Li BUK, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clin Gastroenterol Hepatol.* 2020 Aug;18(9):1987-1994.

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

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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)

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6/15/21 Policy statement added that PENFS, including IB-stim, is considered investigational. Policy Guidelines updated. References added. Medical Director review. Title changed from Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy to Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS). Notification given 6/15/2021 for policy effective date 8/24/2021. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.