

## Corporate Medical Policy

### Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy

<b>File Name:</b>	percutaneous_electrical_nerve_stimulation_(pens)_or_neuromodulation_therapy
<b>Origination:</b>	3/1980
<b>Last CAP Review:</b>	11/2011
<b>Next CAP Review:</b>	11/2012
<b>Last Review:</b>	11/2011

#### Description of Procedure or Service

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##### Description

Percutaneous electrical nerve stimulation is a therapy that combines the features of electroacupuncture and transcutaneous electrical nerve stimulation (TENS). PENS therapy uses fine needle-like electrodes that are placed in close proximity to the painful area and stimulate peripheral sensory nerves in the soft tissue.

##### Background

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 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 electrodes are temporarily placed at specific anatomical landmarks in the deep tissues near the area of the spine that is causing pain (with or without radiating lower extremity pain). Treatment regimens consist of 30-minute sessions, once or twice a week for 8 to 10 sessions.

##### 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 TENS 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.

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## Related Policies

Transcutaneous Electrical Nerve Stimulation (TENS)  
Interferential Stimulation  
Posterior Tibial Nerve Stimulation for Voiding Dysfunction

**\*\*\*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

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**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

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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

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Not applicable.

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

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

## Policy Guidelines

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A literature search found clinical trials using PENS or PNS for the treatment of chronic low back pain, chronic neck pain, diabetic neuropathy, headache, and osteoarthritis of the knee. Study designs appear to have questions regarding the effectiveness of the blinding, control group and short follow up. Many of the studies showed immediate improvement for pain relief versus the placebo effect. The lack of long term outcome data does not establish the effectiveness of PENS or PNT on net health outcomes.

Joint clinical practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicates that there is uncertainty over whether PENS should be considered a novel therapy or a form of

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electroacupuncture. The guidelines conclude that PENS is not widely available. (The guidelines also conclude that TENS has not been proven effective for chronic low back pain).

## **Billing/Coding/Physician Documentation Information**

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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](http://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**

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### **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

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## Policy Implementation/Update Information

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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)

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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.