POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Using mild electrical current is one way to treat nerve pain. It's believed that the electrical signals interfere with the way nerves relay information about pain to the brain. TENS, which uses electricity transferred through the skin, has been in use for decades and is well proven. Newer ways of delivering small electrical impulses are being studied. Percutaneous electrical nerve stimulation (PENS) uses small needles placed just below the skin, with electricity delivered by a battery-powered stimulator. In percutaneous neuromodulation therapy (PNT), fine needle electrodes are placed in deep tissues. Because more high-quality studies are needed to determine if PENS and PNT are effective, they are both still considered unproven.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
Procedure | Investigational
--- | ---
Percutaneous electrical neurostimulation or neuromodulation | Percutaneous electrical neurostimulation or neuromodulation is considered investigational.

Guidelines
Percutaneous electrical neurostimulation (PENS) and percutaneous neuromodulation (PNT) use needle and wire electrodes that are inserted into the skin above a nerve, rather than having electrodes implanted on the skin.

The stimulation devices used in PENS and PNT are also not implanted.

Coding

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<th>CPT</th>
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<td>64999</td>
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Related Information
N/A

Evidence Review

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.

**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.

Percutaneous electrical nerve stimulation (PENS) is similar in concept to transcutaneous electrical nerve stimulation or TENS (see Related Policies) 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 different from acupuncture with electrical stimulation (see Related Policies). 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 needles are placed close to the nerves serving the painful area rather than depending on the theories of energy flow that guide placement of needles for acupuncture.

Percutaneous neuromodulation therapy (PNT) 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.

**Summary of Evidence**

For individuals who have chronic pain conditions (eg, back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) and receive percutaneous electrical nerve stimulation (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 percutaneous neuromodulation therapy, the evidence only 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.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 5 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. The input was mixed regarding whether PENS and PNT should be considered investigational or medically necessary.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

The U.K.’s NICE (National Institute for Health and Care Excellence) published guidance on PENS in 2013.¹⁵ NICE concluded that the current evidence on the safety of PENS for refractory neuropathic pain raises no major safety concerns, that there is evidence of efficacy in the short term and that this procedure may be used with normal arrangements for clinical governance, consent and audit.
American Academy of Neurology et al.

The American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation published an evidence-based guideline on the treatment of painful diabetic neuropathy in 2011.\textsuperscript{16} The guideline concluded that, based on a Class I study, electrical stimulation is probably effective in lessening the pain of diabetic neuropathy and improving quality of life. It was recommended that PENS be considered for the treatment of painful diabetic neuropathy (level B).

American Society of Anesthesiologists et al

The 2010 practice guidelines for chronic pain management from the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine state that subcutaneous peripheral nerve stimulation may be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies (Category B2 evidence, observational studies).\textsuperscript{17}

American College of Physicians and American Pain Society

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 indicate that there is uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture.\textsuperscript{18} 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.)

Medicare National Coverage

The Centers for Medicare and Medicaid Services (CMS) currently has the following national coverage policy on PENS\textsuperscript{19}:

“Electrical nerve stimulation is an accepted modality for assessing a patient’s suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:
B. Percutaneous Electrical Nerve Stimulation (PENS).--This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), 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 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services that are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §280.13 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

Regulatory Status

- Percutaneous Neuromodulation Therapy™ (Vertis Neurosciences) received approval to market by 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 μm (0.736 mm) in length; the patch is reported to feel like sandpaper or Velcro.

FDA product code: NHI.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcutaneous electric nerve stimulation (TENS) or percutaneous electric nerve stimulation (PENS) in the treatment of chronic and postoperative pain TEC Assessments. 1996;Volume 11:Tab 21.


### History

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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

LifeWise Health Plan of Washington complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

LifeWise:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through LifeWise Health Plan of Washington. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-592-6804 (TTY: 800-842-5357).

Arabic:
لا يجوز أن يميّز هذا الإصرار المعلومات حسب العرق أو الجنس أو اللغة وفقاً للقوانين الفيدرالية التي تمنع التمييز. كما أنك مُقرّر للمزيد من المعلومات أو الدعم إثر ذلك، يمكنك الاتصال بمديري المكتب للمساعدة.

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過LifeWise Health Plan of Washington提出的申請或保障的重要訊息。本通知內可能存在重要日期。您可能需要在截止日期前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-592-6804 (TTY: 800-842-5357).

Oromo (Cushite):

French (French):

Deutsche (German):

Hmoob (Hmong):

Ilokno (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impomansan. Daytoy a pakdaar mabalang nga adda ket naglaon iti napateg nga impomansan maipanggamp i aplikasyonoy wenne coveraghe babaen iti LifeWise Health Plan of Washington. Daytoy ket mabalang dagiti importante a peta sa daytoy a pakdaar. Mabalang nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular at a nutuding nga addang tapo mapagatalanayoy nga coverage ti salum-ayto wenne kulog kadagiti gastos. Adda karbenganoy man mangala iti daytoy nga impomansan ken kulog nga pagsasao nga awan ti bayadanyon. Turnawag iti numero nga 800-592-6804 (TTY: 800-842-5357).

Italiano (Italian):
LifeWise Health Plan of Washington announces important information.

This notification may contain important information. Please take action before the deadline.

TTY: 800-842-5357

(Estonian): Vajalik esite esitab olulise info. Palun tegi seda enne kõnelema.

(Telugu): ఇది ప్రాముఖ్యత కలభూషణం ఉంది. ప్రస్తుతం ప్రచుర్యాతమ కాలం పై పాటు సమయం లేదా మరియు అదే ప్రయోగానికి పైన పాటు ఉండడానికి సమయం ఉంది.

(Turkish): İletişim bilgisi içeriyor. Bu bilgiyi almak için belirli bir tarih öncesi yapmanız gerekiyor.

(Tamil): இந்து தவறையின் முக்கியत்துறை செலத்திற்கும் காலம். நேரடி கூறலிருக்கும் காலம் முதல் கூறுவை பெற்றுத் தின்நின்று விளக்குவது உள்ளது.

(Persian): اطلاعیه مهمی از طرف طرح جامع بهداشتی و رفاهی داده می‌شود.

(Polish): Ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez LifeWise Health Plan of Washington. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami.


(Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про ваше звернення щодо страхувального покриття через LifeWise Health Plan of Washington. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Ви треба буде здійснити левичі кроки в конкретній ситуації строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-592-6804 (TTY: 800-842-5357).