

## MEDICAL POLICY – 7.01.588

# Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

BCBSA Ref. Policy: 7.01.29

Effective Date: Oct. 1, 2023  
Last Revised: Sept. 12, 2023  
Replaces: 7.01.29

### RELATED MEDICAL POLICIES:

1.01.24	Interferential Current Stimulation
1.01.507	Electrical Stimulation Devices
2.01.535	Temporomandibular Joint Disorder
7.01.521	Mastectomy for Gynecomastia
8.01.58	Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Select a hyperlink below to be directed to that section.

[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
<ul style="list-style-type: none"><li>• <b>Percutaneous electrical neurostimulation</b></li><li>• <b>Percutaneous neuromodulation therapy</b></li></ul>	<b>Percutaneous electrical neurostimulation or percutaneous neuromodulation therapy is considered investigational.</b>

## Guidelines

**Percutaneous electrical neurostimulation (PENS) and percutaneous neuromodulation therapy (PNT) use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PENS and PNT are not implanted.**

## Coding

Code	Description
<b>CPT</b>	
64999	Unlisted procedure, nervous system

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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 (TENS). PENS is performed with needle electrodes while PNT uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue.

## Background

### Chronic Pain

A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, present a substantial burden to individuals, adversely affecting function and quality of life. Certain racial and ethnic groups are at a higher risk of developing diabetes, which may also put them at higher risk of developing complications from diabetes, such as diabetic neuropathy. According to a 2018 to 2019 National Health Interview Survey and data from the Indian Health Service National Data Warehouse, American Indians and Alaska Natives had the highest reported rate of diagnosed diabetes at 14.5%.<sup>1</sup> This was followed by 12.1% of Black individuals, 11.8% of Hispanic individuals, 9.5% of Asian individuals, and 7.4% of White individuals having diagnosed diabetes in 2018 or 2019.

### Treatment

These chronic pain conditions have typically failed other treatments, and PENS and PNT have been evaluated as treatments to relieve unremitting pain.

PENS is similar in concept to 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 individuals 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 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 (e.g., back, neck, neuropathy, headache, hyperalgesia) who receive PENS, the evidence includes primarily small, controlled trials and two systematic reviews. The relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Two systematic reviews have not revealed consistent benefit from PENS in musculoskeletal pain disorders. One review concluded that PENS could decrease pain intensity but not related disability, while the other found no significant differences between PENS and TENS in mitigation of pain. These conclusions are uncertain due to important methodological limitations in individual trials included in these reviews, such as high heterogeneity with regard to application methods. In the highest quality trial of PENS conducted to date in chronic low back pain, 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 that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions (e.g., knee osteoarthritis) who receive PNT, the evidence consists of a randomized controlled trial (RCT). The 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 that the technology results in an improvement in the net health outcome.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
<a href="#">NCT04243915</a>	Effectiveness of Percutaneous Neuromuscular Electrical Stimulation on Lumbar Multifidus in Combination With a Protocol of Motor Control Exercises in Patients With Chronic Low Back Pain	64	Jun 2024
<a href="#">NCT04442321</a>	Effectiveness of Ultrasound-Guided Percutaneous Electrical Stimulation on Radial Nerve With Exercises in Patients With Lateral Epicondylalgia	60	Sep 2023
<a href="#">NCT04683042</a>	Fibromyalgia TENS in Physical Therapy Study (TIPS): an Embedded Pragmatic Clinical Trial	450	Aug 2024

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## 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 reaffirmed 2011 evidence-based guidelines on the treatment of painful diabetic neuropathy in 2016.<sup>46</sup> The guidelines 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 and recommended that PENS be considered for the treatment of painful diabetic neuropathy (level B). The guidelines were retired and replaced in 2022 with a guideline dedicated to oral

and topical treatment of painful diabetic polyneuropathy.<sup>47</sup> In these updated guidelines, there is no mention of any electrical stimulation strategies for pain.

## **American College of Physicians and American Pain Society**

Joint practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicated uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture.<sup>48</sup> The guidelines concluded that PENS is not widely available. The guidelines also concluded that TENS has not been proven effective for chronic low back pain. These guidelines were updated in 2017 and authors stated that evidence was insufficient to determine harms associated with PENS thus, no recommendation was made.<sup>49</sup>

## **American Society of Anesthesiologists et al**

The 2010 practice guidelines for chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine indicated that subcutaneous peripheral nerve stimulation might 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).<sup>50</sup>

## **National Institute for Health and Care Excellence**

In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS.<sup>51</sup> It concluded that the "Current evidence on the safety of percutaneous electrical nerve stimulation (PENS) for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term."

## **Medicare National Coverage**

The Centers for Medicare and Medicaid Services (CMS) currently has the following national coverage policy on PENS<sup>53</sup>:



"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.

[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."

## 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: "... 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. The 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 1,014 microneedles in a 1.5-inch diameter area. The needles are 736  $\mu\text{m}$  (0.736 mm) in length; the patch is reported to feel like sandpaper or Velcro.

FDA product code: NHI



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## History

Date	Comments
03/13/12	New policy. Add to Surgery section. Removed from 1.01.507.
10/26/12	Replace Policy. Rationale section revised based on literature review through June 2012. References 13 and 16 added; other references renumbered or removed. Policy statement unchanged.
11/20/12	Update Related Policies. Add 8.01.58.
02/14/13	Update Related Policies, title has changed to policy 1.01.24.
09/11/13	Update Related Policies. Add 2.01.21.
09/27/13	Replace policy. Policy updated with literature review through June 4, 2013; reference 17 added; policy statement unchanged.
03/21/14	Update Related Policies. Delete 7.01.106 and replace with 7.01.553.
09/23/14	Annual Review. Policy updated with literature review through June 6, 2014; policy statement unchanged.
03/13/15	Update Related Policies. Remove 1.01.24 as it was archived.
04/17/15	Update Related Policies. Remove 7.01.553 as it was archived.



Date	Comments
09/08/15	Annual Review. Removed CPT codes and descriptions from Policy Guidelines section. Policy updated with literature review through June 9, 2015; no references added. Policy statement unchanged.
09/01/16	Annual Review, approved August 9, 2016. Policy updated with literature review; no references added. Policy statement unchanged.
06/01/17	Annual Review, approved May 2, 2017. Policy moved to new format. Policy updated with literature review through January 26, 2017; some references removed. Minor edits to the Policy section; policy statement otherwise unchanged.
09/01/18	Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; no references added. Policy statement unchanged.
09/01/19	Annual Review, approved August 6, 2019. Policy updated with literature review through April 2018; no references added. Policy statement unchanged.
09/01/20	Annual Review, approved August 4, 2020. Policy updated with literature review through April, 2020; no references added. Policy statement unchanged.
09/01/21	Annual Review, approved August 3, 2021. Policy updated with literature review through April 28, 2021; references added. Policy statement unchanged.
08/01/22	Annual Review, approved July 25, 2022. Policy updated with literature review through May 5, 2022; references added. Policy statements unchanged.
10/01/23	Policy renumbered, approved September 12, 2023, from 7.01.29 to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy. Policy updated with literature review through June 7, 2023; references added. Policy statement unchanged.

**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). ©2023 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.



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**Washington residents:** You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/online-services/cc/pub/complaintinformation.aspx>.

**Alaska residents:** Contact the Alaska Division of Insurance via email at [insurance@alaska.gov](mailto:insurance@alaska.gov), or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

## Language Assistance

**ATENCIÓN:** si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

**PAUNAWA:** Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

**注意:** 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。

**CHÚ Ý:** Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

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**ВНИМАНИЕ:** Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

**LUS CEEV:** Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

**MO LOU SILAFIA:** Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totagi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

**ໂປດຊາບ:** ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າ, ຄມມຸນມີພ້ອມໃຫ້ທ່ານ. ໂທ 800-722-1471 (TTY: 711).

**注意事項:** 日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 (TTY: 711) まで、お電話にてご連絡ください。

**PAKDAAR:** Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

**УВАГА!** Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

**ប្រយ័ត្ន:** បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

**ማስታወሻ:** የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም አርዳታ ድርጅቶች በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው: 711)፡

**XIYYEEFFANNAA:** Afaan dubbattu Oroomiffa, tajaajjila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

**ملحوظة:** إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

**मिथान सिछि:** ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

**เรียน:** ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

**UWAGA:** Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

**ATANSYON:** Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

**ATTENTION:** Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS: 711).

**ATENÇÃO:** Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

**ATTENZIONE:** In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

**توجہ:** اگر بہ زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.