MEDICAL POLICY – 7.01.29
Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

BCBSA Ref. Policy: 7.01.29

Effective Date: Sept. 1, 2018
Last Revised: Aug. 10, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.507 Electrical Stimulation Devices
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.
### Procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous electrical neurostimulation or</td>
<td>Percutaneous electrical neurostimulation or percutaneous neuromodulation therapy is considered investigational.</td>
</tr>
<tr>
<td>percutaneous neuromodulation</td>
<td></td>
</tr>
</tbody>
</table>

### 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 percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Unlisted procedure, nervous system</td>
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### Related Information

N/A

### Evidence Review
Description

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. PENS is performed with needle electrodes while percutaneous neuromodulation therapy 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, presents a substantial burden to patients, adversely affecting function and quality of life.

Treatment

These chronic pain conditions have typically failed other treatments, and percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) have been evaluated as treatments to relieve unremitting pain.

PENS is similar in concept to transcutaneous electrical nerve stimulation (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 transcutaneous electrical nerve stimulation. 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 (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 percutaneous neuromodulation therapy, the evidence consists of a 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03331055</td>
<td>Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for Pain in Patients With Pancreatic Cancer</td>
<td>36</td>
<td>Oct 2019</td>
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<tr>
<td>NCT03338543</td>
<td>Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for Pain in Patients With Liver Cancer</td>
<td>36</td>
<td>Oct 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, 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. Input was mixed on whether percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy should be considered investigational or medically necessary.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2013) published guidance on percutaneous electrical nerve stimulation (PENS). 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.”

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. 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).
**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).\(^\text{16}\)

**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.\(^\text{17}\) The guidelines concluded that PENS is not widely available. (The guidelines also concluded that transcutaneous electrical nerve stimulation 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\(^\text{18}\):

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)

The 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) the U.S. Food and Drug Administration (FDA). 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 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.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>11/20/12</td>
<td>Update Related Policies. Add 8.01.58.</td>
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<td>02/14/13</td>
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<td>Replace policy. Policy updated with literature review through June 4, 2013; reference 17 added; policy statement unchanged.</td>
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<td>06/01/17</td>
<td>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.</td>
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<td>09/01/18</td>
<td>Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; no references added. Policy statement unchanged.</td>
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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). ©2018 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

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

Premera:
- 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 Premera 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 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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 S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action before a certain date, to keep your health insurance or benefits. You have the right to get this information in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):

French (French):
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konèsan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksoyon avan sèten dat limit pou ka kente kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou pèye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmooj (Hmong):
Tsab ntaww tshaj xo no muaj cov ntshiab lus tsen ceb. Tej zaum tsab ntaww tshaj xo no muaj cov ntsiab lus tsen ceb bjo kog dain ntaww thov kev pab los yoj kog qhov kev pab cuam los ntaww Premera Blue Cross. Tej zaum muaj cov hnb tseem ceb uas sau rau hauv daim ntaww no. Tej zaum koj koy yuav ta uu que yam uas peb kom koj uas tsib pub dhuav cov caij nyoy uas teev txog rau hauv daim ntaww no mas koi koi yuav yuav ta baiis kev pab cuam kham muo los yoj kev yuav pab tem tej nqi kho mbo ntaww. Koi muaj cai kom laww muab cov ntshiab lus no us sau mbu sau uas koi hom lus pub daww rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impomarsion. Daytoy a pakdaar mabalini nga adda ket naglaon iti napateg nga impomarsion maiyandegge iti aplikasyonu yenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelta iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramidenyo nga addang sakkay dagiti partikular a naituding ti coverage ti salun-atyo yenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tulong iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross provides important information about emergency care.

The provider is Premera Blue Cross. Please call 800-722-1471 (TTY: 800-842-5357) for more information.

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

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Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Panawana na ito ay naglalaman ng mahalagang impormasyon. Ang panawana na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagkakaparangal sa pagkakapatrola ng Premera Blue Cross. Maaaring may mga mahalagang pahinag o sa paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon. Umo-on ka ng numero 800-722-1471 (TTY: 800-842-5357).