Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy # 00144
Original Effective Date: 11/29/2004
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Electrical Nerve Stimulation Devices is addressed separately in medical policy 00142.

Note: Temporomandibular Joint Dysfunction is addressed separately in medical policy 00583.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers percutaneous electrical neurostimulation (PENS) or percutaneous neuromodulation therapy (PNT) to be **investigational.***

Background/Overview

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 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 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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. 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 1014 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.

Rationale/Source

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.

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.

Supplemental Information

Clinical Input 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, American Association of Neuromuscular and Electrodiagnostic Medicine, and 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).

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. 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.)

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The Centers for Medicare & Medicaid Services currently has the following national coverage policy on PENS:

"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.

[I]t 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".

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03331055	Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for	36	Oct 2019

	Pain in Patients With Pancreatic Cancer		
NCT03338543	Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for Pain in Patients With Liver Cancer	36	Oct 2019

NCT: national clinical trial.

References

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6. Ghoname EA, White PF, Ahmed HE, et al. Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica. Pain. Nov 1999;83(2):193-199. PMID 10534590
7. Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. JAMA. Mar 3 1999;281(9):818-823. PMID 10071003

8. Hamza MA, Ghoname EA, White PF, et al. Effect of the duration of electrical stimulation on the analgesic response in patients with low back pain. Anesthesiology. Dec 1999;91(6):1622-1627. PMID 10598602
9. Ghoname ES, Craig WF, White PF, et al. The effect of stimulus frequency on the analgesic response to percutaneous electrical nerve stimulation in patients with chronic low back pain. Anesth Analg. Apr 1999;88(4):841-846. PMID 10195535
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15. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010;112(4):810-833. PMID 20124882
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17. Centers for Medicare & Medicaid. National Coverage Determination (NCD) for Assessing Patient's Suitability for ELECTRICAL NERVE STIMULATION Therapy (160.7.1). 2006; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=63&ncdver=2&CoverageSelection=National&KeyWord=Electrical+Nerv

e+Stimulation&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAABAAAAAA&.

Policy History

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10/05/2004	Medical Director review
10/19/2004	Medical Policy Committee review
11/29/2004	Managed Care Advisory Council approval
06/01/2006	Format revision, including addition of FDA and or other governmental regulatory approval. Coverage eligibility unchanged.
12/01/2006	Medical Director review
12/20/2006	Medical Policy Committee approval. Coverage eligibility unchanged.
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/31/2010	Coding updated
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.

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11/03/2016 Medical Policy Committee review
11/16/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017 Medical Policy Committee review
11/15/2017 Medical Policy Implementation Committee approval. No change to coverage.
11/08/2018 Medical Policy Committee review
11/21/2018 Medical Policy Implementation Committee approval. No change to coverage. FDA updated.
11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. No change to coverage.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 04/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64555, 64585, 64999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.