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

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 11/16/2016

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.

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 or neuromodulation to be investigative.*

Background/Overview
Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT™) are therapies that combine the features of electroacupuncture and transcutaneous electrical nerve stimulation (TENS). Percutaneous electrical nerve stimulation is performed with a few needle electrodes while PNT uses very fine needle-like electrode arrays that are placed in close proximity to the painful area to stimulate peripheral sensory nerves in the soft tissue.

Percutaneous electrical nerve stimulation 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 are then stimulated. PENS is generally reserved for patients who fail to get pain relief from TENS. Percutaneous electrical nerve stimulation 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 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Percutaneous Neuromodulation Therapy (Vertis Neurosciences) received approval to market by the FDA through the 510(k) process in 2002. The labeled indication reads as follows, 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
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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.

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

35-46 ASSESSING PATIENT'S SUITABILITY FOR ELECTRICAL NERVE STIMULATION THERAPY

"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:

Percutaneous Electrical Nerve Stimulation
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, 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 one 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) 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.)"

Rationale/Source
This policy was originally based on a 1996 TEC Assessment of PENS for the treatment of chronic pain. The objective of the 1996 Assessment was to determine if the effects of PENS exceed placebo effects. The following study selection criteria were used in the 1996 TEC Assessment:

- Study contained original empirical data;
- Study design included a treatment group and a control group;
- Study reported on a health outcome relevant to the pain condition treated; and
No clinical studies of PENS were identified by the 1996 Assessment, thus no conclusions about effectiveness could be reached. Subsequently, the policy was updated with a literature review covering the period between January 1996 and February 2004. The 2004 review showed that evidence was still inadequate to reach conclusions about the effectiveness of PENS for the treatment of chronic pain. The literature search revealed 8 randomized trials meeting the cited criteria. Of the 8, a total of 5 addressed use of PENS in treating chronic back pain. A single study focused on each of these conditions: chronic neck pain, chronic diabetic neuropathy, and chronic headache. All were designed as randomized crossover studies in which sham PENS was compared with between 1 and 3 types of active PENS, in addition to alternative treatments such as TENS or exercise therapy. All 8 studies were conducted at 1 institution, the University of Texas Southwestern Medical Center in Dallas.

Since 2004, the literature for this policy has been periodically updated using the MEDLINE database. The most recent literature review was performed through June 9, 2015. Following are key studies to date.

**Percutaneous Electrical Nerve Stimulation**

**Chronic Low Back Pain**

In 2008, Weiner et al reported a trial with 200 older adults, which had been funded by the National Institutes of Health. Subjects with chronic lower back pain were randomized to PENS or sham-control treatment, with or without physical conditioning/aerobic exercise, twice a week for 6 weeks. Thus, the 4 treatment groups were PENS alone, sham PENS alone, PENS plus physical conditioning, or sham PENS plus physical conditioning. The sham control condition consisted of 10 acupuncture needles in identical locations, depth, and duration (30 minutes) as the PENS needles, with brief (5-minute) stimulation at 2 additional needles. Primary and secondary outcome measures were collected at baseline, 1 week, and 6 months after treatment by a research associate who was unaware of the treatment. There were no significant adverse effects and also no differences between the PENS and sham PENS groups in any outcome measure at 1-week or 6-month follow-up. All 4 groups reported reduced pain of a similar level (improvement ranging from 2.3 to 4.1 on the McGill Pain Questionnaire), reduced disability (range, 2.1-3.0, on the Roland scale) and improved gait velocity (0.04-0.07 m/s) that was maintained for 6 months. Although the authors concluded that minimal electrical stimulation (5 minutes at 2 needles) is as effective as usual PENS (30 minutes of stimulation from 10 needles), the lack of benefit of this treatment over sham control does not provide support for use of PENS in patients with chronic low back pain.

Yokoyama et al found patients randomized to PENS treatment twice per week for 8 weeks had significantly decreased pain levels, physical impairment, and nonsteroidal anti-inflammatory drug use, which continued to be present 1 month after treatment completion compared with a second group that received PENS for 4 weeks followed by TENS for 4 weeks and a third group that received only TENS for 8 weeks. While PENS treatment for 8 weeks seemed to demonstrate greater effectiveness in controlling pain for up to 1 month after treatment when compared with the other treatment groups, the beneficial effects were not found at the 2-month follow-up.
Ghoname et al compared sham PENS, active PENS, and TENS in 64 patients. Active PENS achieved better outcomes than sham PENS on visual analog scale (VAS) pain scores and daily oral analgesic requirement. Active PENS was better than sham PENS and TENS on physical activity, quality of sleep, and preference. Ghoname et al administered sham PENS, active PENS, TENS, and exercise therapy in 60 patients. Active PENS resulted in better outcomes than all other modalities in terms of VAS pain, analgesic requirements, physical activity, quality of sleep, and preference. Hamza et al varied the duration of active electrical stimulation at 3 levels (15, 30, 45 minutes) and compared them with sham stimulation in 75 patients. These investigators confirmed that sham PENS had the least effect, and results were best when the stimulation lasted 30 or 45 minutes. Ghoname et al varied the frequency of the active electrical stimulus at 3 levels, also comparing it with sham stimulation, in 68 patients. One level involved active stimulation with alternating 15-Hz and 30-Hz frequencies, while the other active levels had frequencies of 4 Hz and 100 Hz. The alternating frequency technique had the best results, superior to sham PENS. White et al did not include sham PENS in a study of 72 patients. Rather, this study compared 4 montages, or patterns of needle placement. They found that a bottle-shaped pattern achieved the best results, compared with 3 other patterns. In addition, a 2003 study focused on chronic low back pain in community-dwelling older adults. Patients were randomized to receive twice weekly PENS or sham PENS for 6 weeks. At 3-month follow-up, the treatment group reported a significant reduction in pain intensity and disability, while the control group did not.

Section Summary
The highest quality trial on PENS for chronic low back pain found no difference between the active (30 minutes from 10 needles) and sham PENS (5 minutes from 2 needles) at 1 week or 6 months after treatment. While other studies suggest that active PENS has effects that exceed placebo PENS in the short term, they did not address long-term improvement of pain and functional outcomes, the objective of treating chronic low back pain. It is also unclear whether these study designs included adequate blinding or whether patients withdrew from these studies.

Chronic Neck Pain
One study by White et al compared 2 locations of active stimulation with sham stimulation in 68 patients. Local stimulation involved needle insertion at the neck, while remote stimulation entailed needles placed in the lower back. The sham condition received needles with no electrical stimulation at the neck. Outcomes were assessed immediately after completion of a 3-week treatment period. The local placement of active needles resulted in better pain relief, physical activity, quality of sleep, and analgesic use than local sham treatment or remote active treatment. The authors stated that no adverse effects were observed at needle insertion sites. The study was described as investigator blinded, but no details were given about the method of blinding. Withdrawals were not noted, and no long-term outcome data were presented. This single study, in which blinding is of uncertain adequacy, does not permit conclusions about the effectiveness of PENS for treating chronic neck pain.

Diabetic Neuropathy
In a crossover study by Hamza et al, 50 patients with diabetic neuropathic pain for at least 6 months were randomized to receive either sham PENS or active PENS first in a 7-week study. Outcome was assessed 1 day after completion of a 3-week treatment period. Active PENS resulted in better outcomes on VAS pain,
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activity, sleep, and analgesic use, compared with sham PENS. The authors describe the study as investigator-blinded, without providing details of how blinding was attempted. Thus, it is uncertain whether blinding was adequate. Withdrawals were not mentioned. Also, no long-term outcome data were presented, so long-term effects are unknown. This single study, which may not have been adequately blinded, does not allow conclusions about the effects of PENS for treating diabetic neuropathy.

Headache
Ahmed et al conducted a crossover study in 30 patients with longstanding headaches of 3 types: tension, migraine, and posttraumatic injury. Two-week courses of active and sham PENS were compared. Outcomes were assessed at the completion of each treatment. Active PENS achieved better outcomes than sham PENS in terms of VAS pain, physical activity, and quality of sleep. Results did not vary by headache type. The investigators stated that the study was single-blinded but gave no details about blinding methods or whether withdrawals occurred. The report offers no long-term outcome data. This study does not establish the effectiveness of PENS for treatment of chronic headache.

Chronic Surface Hyperalgesia
Raphael et al reported a multicenter double-blinded randomized crossover trial of a single PENS treatment compared with a sham treatment in 30 patients with surface hyperalgesia due to a variety of chronic pain conditions. The pain diagnoses included surgical scar pain, occipital neuralgia, posttraumatic neuropathic pain, stump pain, inflammatory neuropathic pain, chronic low back pain, complex regional pain syndrome, pain following total knee arthroplasty (TKA), chronic cervical pain, and postherpetic neuralgia. The duration of pain ranged from 1 to 35 years, with a mean of 8.1 years. Subjective pain on a numeric rating scale (NRS) and a pressure pain threshold were measured before and 1 week after the single treatment, with a washout period of 4 weeks between treatments. The median NRS improved from 7.5 to 0.5 after active PENS and did not change after sham treatment (7.5 pre, 7.5 post). The mean pain pressure threshold improved from 202 g to 626 gm after active PENS and did not change significantly after sham treatment (202 g pre, 206 g post). Blinding was maintained after the first treatment, but not after the second due to the tingling sensation with active PENS. Analysis of the first treatment showed a significant difference in change of the NRS (3.9 vs 0.1) and in the pain pressure threshold (310 g vs 8 g) for the active compared with sham treatment. Longer term follow-up in a larger sample of patients is needed to evaluate the efficacy of this treatment approach to chronic hyperalgesia.

Percutaneous Neuromodulation Therapy
Chronic Low Back Pain
From its description, PNT appears to be a variant of PENS, varying in length and number of the needles. A literature search identified 1 abstract focusing on neuromodulation for chronic low back pain. This study was an uncontrolled case series of 83 patients with low back pain. While pain improved at 5-week follow-up, the lack of a control group precludes scientific assessment.

Osteoarthritis of the Knee
In 2007, Kang et al reported a single-blinded trial that included 70 patients with knee osteoarthritis randomized to stimulation (at the highest tolerable intensity) or placement of electrodes (without stimulation). Patients in the sham group were informed that they would not perceive the normal “pins and needles” sensation. Only 59 patients completed the study. The mean pain intensity was 5.5 pre and 2.5 post for active stimulation and 5.5 pre and 5.5 post for sham stimulation. The authors reported the study as investigator-blinded, though they did not provide details of how blinding was attempted. The study did not provide long-term outcome data, leaving uncertainty about the efficacy of this treatment approach to osteoarthritis of the knee.
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needles” with this new device. Patients received 1 treatment and were followed up for 1 week. The neuromodulation group had 100% follow-up; 7 of 35 (20%) patients from the sham group dropped out. VAS pain scores improved immediately after active (from 5.4 to 3.2), but not sham (5.6 to 4.9) treatments. VAS scores (4.6 vs 5.2, respectively) were not significantly different for the 2 groups at 48 hours after treatment. Changes in the Western Ontario and McMaster Osteoarthritis Index were significantly better for the category of stiffness (1-point change vs 0-point change) but not for pain or function at 48 hours. Measures of patient satisfaction were significantly higher in the neuromodulation group (eg, 77% vs 11% good to excellent, respectively) at up to 1-week follow-up. Interpretation is limited by the discrepancy between patient satisfaction ratings and 48-hour VAS pain scores and the differential loss to follow-up in the 2 groups. These results raise questions about the effectiveness of the blinding, the contribution of short-term pain relief and placebo effects, and the duration of the treatment effects.

Acute Postoperative Pain
A small (N=23) single-blinded RCT was published in 2011 that assessed the efficacy of PNT to control acute pain after TKA. Twice daily PNT or sham treatments were begun following removal of the epidural at 36 to 48 hours postsurgery and continued until hospital discharge. The average length of stay was 4.36 days in the PNT group and 3.9 days in the control group. All patients randomized to the control group completed the study, while 2 participants from the experimental group withdrew due to unwillingness to comply with twice daily treatments. Before and after each treatment, patients completed a Brief Pain Inventory, which included a VAS pain score. The VAS pain score decreased from 28 to 19 after PNT (32% decrease), but did not change significantly in the control group (26 pre- and 25 posttreatment). Results for the Brief Pain Inventory were not reported. There was a trend (p=0.09) for decreased opioid use in the PNT group compared with controls. Post hoc power analysis indicated that the study was underpowered. Additional limitations are the lack of investigator blinding and measurement of outcomes immediately after treatment. The authors indicate that a larger trial is planned.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

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NCT: national clinical trial.

° Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
The literature on PENS and PNT consists primarily of small controlled trials with unclear blinding and short follow-up. In the highest quality trial of PENS conducted to date, no difference in outcomes was found between the active (30 minutes of stimulation at 10 needles) and the sham (5 minutes of stimulation at 2 needles) treatments. Literature searches have identified only 2 small trials on PNT, and clinical input on the
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The efficacy of PENS and PNT was mixed. The available evidence is insufficient to permit conclusions concerning the effect of this procedure on health outcomes.

References

2. 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.
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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
12/03/2008    Medical Director review
12/17/2008    Medical Policy Committee approval. No change to coverage eligibility.
10/14/2010    Medical Policy Committee review
12/31/2010    Coding updated
10/06/2011    Medical Policy Committee review
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.
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

Next Scheduled Review Date:  11/2017

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<td>No codes</td>
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<td>ICD-10 Diagnosis</td>
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*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:

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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:

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