



# Louisiana

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

**Policy #** 00144

**Original Effective Date:** 11/29/2004

**Current Effective Date:** 11/21/2018

*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 (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 PENS and 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 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 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.

A recently FDA approved PNFS device is the NSS-2 Bridge (Innovative Health Solutions Inc., Indianapolis, IN). The Bridge is a battery-powered percutaneous nerve field stimulator (PNFS) proposed to be used as an aid to reduce the symptoms of opioid withdrawal. The device contains a battery-powered chip that emits electrical pulses to stimulate branches of cranial nerves V, VII, IX, X and the occipital nerves. Patients can use the device for up to five days during acute symptoms (e.g., sweating, gastrointestinal upset, agitation,

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insomnia and joint pain) that may be experienced during the physical withdrawal phase. NSS-2 was originally created to alleviate soreness and chronic pain. The NSS-2 Bridge is worn behind the ear and requires a prescription (Hayes, 2017; Innovative Health, 2018).

## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

The FDA approved the NSS-2 Bridge device as a 510(k) Class II percutaneous nerve stimulator for substance use disorders. FDA identifies this generic type of device as a “percutaneous nerve stimulator for substance use disorders. A percutaneous nerve stimulator for substance use disorders is a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders” (FDA, 2017).

Centers for Medicare and Medicaid Services (CMS)

The CMS 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”.

## **Rationale/Source**

The review was initially informed by a TEC Assessment (1996) on PENS for the treatment of chronic pain.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to

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function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

### **PERCUTANEOUS ELECTRICAL NERVE STIMULATION AND PERCUTANEOUS NEUROMODULATION THERAPY**

#### **Clinical Context and Therapy Purpose**

The purpose of PENS and percutaneous neuromodulation therapy (PNT) in patients who have pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Do PENS or PNT improve the net health outcome in patients with chronic musculoskeletal or neuropathic pain?

The following PICOTS were used to select literature to inform this review.

#### ***Patients***

The relevant populations of interest are patients with chronic musculoskeletal or neuropathic pain conditions including low back pain, neck pain, diabetic neuropathy, chronic headache, surface hyperalgesia, and knee osteoarthritis.

#### ***Interventions***

The therapies being considered are PENS and PNT.

#### ***Comparators***

The following practice is currently being used: continued medical management of chronic musculoskeletal or neuropathic pain conditions.

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### **Outcomes**

The general outcomes of interest are pain as measured by a visual analog score (VAS) or numeric rating scale (NRS) and function may be measured by physical activity and sleep quality. For example, pain and function in osteoarthritis are measured by the Western Ontario and McMaster Osteoarthritis Index.

### **Timing**

The time of assessment is immediately after treatment for acute effects, with follow-up for months to evaluate the effects of chronic pain.

### **Setting**

The setting is a pain clinic.

## **Percutaneous Electrical Nerve Stimulation**

### **Chronic Low Back Pain**

Weiner et al (2008) reported on a randomized controlled trial with 200 older adults, which was funded by the National Institutes of Health. Subjects with chronic low 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 from 2 additional needles. Primary and secondary outcome measures were collected at baseline, 1 week, and 6 months after treatment by a research associate unaware of the treatment. There were no significant adverse events and 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-Morris Disability Questionnaire), and improved gait velocity (0.04-0.07 m/s) that was maintained for 6 months. Although trialists concluded that minimal electrical stimulation (5 minutes with 2 needles) was as effective as usual PENS (30 minutes of stimulation with 10 needles), the lack of benefit of this treatment over the sham-control did not support the use of PENS in patients with chronic low back pain.

An earlier study by Weiner et al (2003) focused on chronic low back pain in 34 community-dwelling older adults. Patients were randomized to 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. Yokoyama et al (2004) used an active control of transcutaneous electrical nerve stimulation (TENS) in a study with 53 patients. They reported that patients randomized to PENS twice weekly for 8 weeks (n=18) had significantly decreased pain levels, physical impairment, and nonsteroidal anti-inflammatory drug use, which continued 1 month after treatment completion compared with a second group that received PENS for 4 weeks, followed by TENS for 4 weeks (n=17), and a third group that received only TENS for 8 weeks (n=18). While PENS for 8 weeks seemed to demonstrate greater effectiveness in controlling pain for

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up to 1 month after treatment compared with the other treatment groups, the beneficial effects were not found at the 2-month follow-up.

Several studies were reported by a single academic research. One of the reports, by Ghoname et al (1999), compared sham PENS, active PENS, and TENS in 64 patients. Active PENS achieved better outcomes than sham PENS on VAS pain scores and daily oral analgesic requirements and was better than sham PENS and TENS on physical activity, quality of sleep, and preference. Another report by Ghoname et al (1999) compared sham PENS, active PENS, TENS, and exercise therapy in 60 patients. Active PENS resulted in better outcomes than all other modalities regarding VAS pain, reduction in analgesic requirements, physical activity, quality of sleep, and preference. Hamza et al (1999) 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 (1999) varied the frequency of the active electrical stimulus, 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.

### **Opioid Withdrawal:**

Published studies investigating the safety and effectiveness of the NSS-2 Bridge are primarily in the form of retrospective reviews with small patient populations (n=73) (Miranda and Taca, 2018). There is currently insufficient evidence to support the use of this device for any indication including the treatment of chronic pain and opioid withdrawal.

### *Subsection Summary: Chronic Low Back Pain*

The largest double-blinded, sham-controlled trial on PENS for chronic low back pain found no difference between the active (30 minutes with 10 needles) and sham PENS (5 minutes with 2 needles) at 1 week or 6 months after treatment. While other smaller studies have suggested that active PENS has effects that exceed placebo PENS in the short term, the trialists did not address long-term improvements in pain and functional outcomes, the objective of treating chronic low back pain. No studies on PENS for low back pain have been identified in the last decade.

### **Chronic Neck Pain**

One study by White et al (2000) 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 the local sham treatment or remote active treatment. The study was described as investigator-blinded. Withdrawals were not noted, and no long-term outcome data were presented.

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*Subsection Summary: Chronic Neck Pain*

This single study with short-term follow-up does not permit conclusions on the effectiveness of PENS for treating chronic neck pain.

**Diabetic Neuropathy**

In a crossover study by Hamza et al (2000), 50 patients with diabetic neuropathic pain for at least 6 months were randomized to sham PENS or active PENS in a 7-week study. Outcomes were assessed 1 day after completion of a 3-week treatment period. Active PENS had better results on VAS pain, activity, sleep, and analgesic use than sham PENS. The authors described the study as investigator-blinded. No long-term outcome data were presented.

*Subsection Summary: Diabetic Neuropathy*

This single study does not permit conclusions on the effects of PENS for treating diabetic neuropathy.

**Headache**

Ahmed et al (2000) 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 regarding 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 did not offer long-term outcomes data.

*Subsection Summary: Headache*

This single study does not establish the effectiveness of PENS for treatment of a chronic headache.

**Chronic Surface Hyperalgesia**

Raphael et al (2011) reported on 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, chronic cervical pain, and postherpetic neuralgia. The duration of pain ranged from 1 to 35 years (mean, 8.1 years). Subjective pain on an 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. Median NRS scores 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 to 626 grams after active PENS and did not change significantly after sham treatment (202 grams pre, 206 grams 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 NRS score change (3.9 vs 0.1) and the pain pressure threshold (310 g vs 8 g) for the active compared with sham treatment.

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### *Subsection Summary: Chronic Surface Hyperalgesia*

A single study has reported positive effects on PENS for chronic surface hyperalgesia. Longer term follow-up in a larger sample is needed to evaluate the efficacy and confirm clinically meaningful durability of this treatment approach.

### **Section Summary: Percutaneous Electrical Nerve Stimulation**

The highest quality trial on PENS for chronic pain found no difference between the active (30 minutes with 10 needles) and sham PENS (5 minutes with 2 needles) at 1 week or 6 months posttreatment. While other smaller studies have suggested that active PENS has effects that exceed sham in the short term, none addressed long-term reductions in pain and improvements in functional outcomes, the objective of treating chronic pain. Most of the studies on PENS were reported by a single academic research group (including Ghoname, Hamza, Ahmed, and White) over a decade ago. A more recent study has reported positive effects on PENS for chronic surface hyperalgesia at 1 week after treatment. Longer term follow-up in a larger sample of patients is needed to evaluate the efficacy and confirm clinically meaningful durability of this treatment approach.

## **Percutaneous Neuromodulation Therapy**

### ***Knee Osteoarthritis***

Kang et al (2007) reported on 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” with this new device. Patients received 1 treatment and were followed for 1 week. The neuromodulation group had 100% follow-up; 7 (20%) of 35 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 did not differ significantly between the 2 groups at 48 hours posttreatment. Changes in the Western Ontario and McMaster Osteoarthritis Index scores were significantly better for stiffness (1-point change vs 0-point change) but not for pain or function at 48 hours.

### *Section Summary: Percutaneous Neuromodulation Therapy*

One study was identified on PNT for osteoarthritis of the knee. Interpretation of this trial is limited by its lack of investigator blinding and 48-hour VAS pain scores and a 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 PNT treatment effects.

## **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

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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.

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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.
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

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11/21/2018 Medical Policy Implementation Committee approval. No change to coverage. FDA updated.  
Next Scheduled Review Date: 11/2019

### **Coding**

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Code Type	Code
CPT	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. 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.

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# Louisiana

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

Policy # 00144

Original Effective Date: 11/29/2004

Current Effective Date: 11/21/2018

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

**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.

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