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

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 11/15/2017

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 percutaneous neuromodulation therapy to be investigational.*

Background/Overview
Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) been evaluated for the treatment of a variety of chronic musculoskeletal or neuropathic pain conditions including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia. Chronic pain presents a substantial burden to patients, adversely affecting function and quality of life. These chronic pain conditions have typically failed other treatments, and the goal of treatment with PENS and PNT is 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.

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. FDA through the 510(k) process. The labeled indication is: “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.” In 2006, the Deepwave™ Percutaneous Neuromodulation Pain Therapy System (Biowave) was cleared for marketing by FDA through the 510(k) process. FDA determined
Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 11/15/2017

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.

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.

As in the case of TENS ([transcutaneous electrical nerve stimulation] described in subsection A), 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 1 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)(1) 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
Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. It is recognized that RCTs are extremely important to assess treatments of painful conditions and low back pain in particular, due to the expected placebo effect, the subjective nature of pain assessment in general, and the variable natural history of chronic pain that often responds to conservative care. Therefore, this evidence review focuses on RCTs. Following are key studies to date.

PERCUTANEOUS ELECTRICAL NERVE STIMULATION

Chronic Low Back Pain
In 2008, Weiner et al reported on an RCT 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 effects 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 use of PENS in patients with chronic low back pain.

A 2003 study by Weiner et al 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 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 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 in 1999. One of the reports by 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 requirements and was better than sham PENS and TENS on physical activity, quality of sleep, and preference. Another report by Ghoname et al compared 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, 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.

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, they did not address long-term improvement of 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.

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 to active PENS first 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, so long-term effects are unknown.
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 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 did not offer long-term outcomes data.

Subsection Summary: Headache
This single study does not establish the effectiveness of PENS for treatment of 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 (TKA), chronic cervical pain, and postherpetic neuralgia. The duration of pain ranged from 1 to 35 years (mean, 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. 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 in the pain pressure threshold (310 g vs 8 g) for the active compared with sham treatment.

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, they did not address long-term improvements in pain and functional outcomes, the objective of treating chronic pain. Most of the studies on PENS were reported by a single academic research group (including Ghoname,
Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 11/15/2017

Hamza, Ahmed, and White) over a decade ago. One more recent study have 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
Chronic Low Back Pain
From its description, PNT appears to be a variant of PENS, varying in length and number of needles used. 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 the 5-week follow-up, the lack of a control group and complete reporting preclude scientific assessment.

Osteoarthritis of the Knee
In 2007, Kang et al 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 up 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 were significantly better for 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.

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, discrepancy between patient satisfaction ratings 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 the treatment effects.

SUMMARY OF EVIDENCE
For individuals who have chronic pain conditions (eg, back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) 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.
Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy #  00144  
Original Effective Date:  11/29/2004  
Current Effective Date:  11/15/2017

For individuals who have chronic pain conditions (eg, back, neck, neuropathy, headache, hyperalgesia, knee osteoarthritis) who receive percutaneous neuromodulation therapy, the evidence consists of 1 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.

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.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy #  00144
Original Effective Date:  11/29/2004
Current Effective Date:  11/15/2017


Policy History
Original Effective Date:  11/29/2004
Current Effective Date:  11/15/2017
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
11/02/2017  Medical Policy Committee review
11/15/2017  Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date:  11/2018

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 2016 by the American Medical Association (AMA).

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 11/15/2017

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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which 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:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>64999</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*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.

‡ 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.