

<b>7.01.29</b>	<b>Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy</b>		
<b>Original Policy Date:</b>	July 31, 2015	<b>Effective Date:</b>	September 1, 2019
<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 10

### Policy Statement

Percutaneous electrical neurostimulation or percutaneous neuromodulation therapy is considered **investigational**.

### Policy Guidelines

The following is the correct CPT code to use for percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT):

- **64999:** Unlisted procedure, nervous system

CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64561) are not appropriate, because percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted, so CPT code 64590 is also not appropriate.

### Description

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. PENS is performed with needle electrodes while percutaneous neuromodulation therapy uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue.

### Related Policies

- Cranial Electrotherapy Stimulation and Auricular Electrostimulation
- Interferential Current Stimulation
- Peripheral Subcutaneous Field Stimulation
- Temporomandibular Joint Disorder
- Transcutaneous Electrical Nerve Stimulation

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

In 2002, the Percutaneous Neuromodulation Therapy™ (Vertis Neuroscience) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The labeled indication is: "... for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain." In 2006, the Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave) was cleared for marketing by the FDA through the 510(k) process. The 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

### Background

#### Chronic Pain

A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, presents a substantial burden to patients, adversely affecting function and quality of life.

#### Treatment

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

PENS is similar in concept to transcutaneous electrical nerve stimulation (see Blue Shield of California Medical Policy: 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.

### Literature Review

The review was initially informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (1996) on percutaneous electrical nerve stimulation (PENS) for the treatment of chronic pain.<sup>1</sup>

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 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.

### **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.

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

## **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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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. One of the reports, by Ghoname et al (1999), compared sham PENS, active PENS, and TENS in 64 patients.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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, 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.<sup>9</sup> 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 active PENS in a 7-week study.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup> 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.

### **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).<sup>12</sup> 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 (e.g., 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 (e.g., 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 from Blue Cross Blue Shield Association, input was received from 5 physician specialty societies and 2 academic medical centers 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).<sup>13</sup> 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.<sup>15</sup> 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).<sup>14</sup>

### **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.<sup>15</sup> 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<sup>16</sup>:

"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.

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".

## 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
<b>Ongoing</b>			
NCT03331055	Percutaneous Electrical Nerve Stimulation or Transcutaneous Electrical Nerve Stimulation for Pain in Patients With Pancreatic Cancer	36	Oct 2019
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

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcutaneous electric nerve stimulation (TENS) or percutaneous electric nerve stimulation (PENS) in the treatment of chronic and postoperative pain TEC Assessments. 1996;Volume 11:Tab 21.
2. Weiner DK, Perera S, Rudy TE, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. *Pain*. Nov 30 2008;140(2):344-357. PMID 18930352
3. Weiner DK, Rudy TE, Glick RM, et al. Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults. *J Am Geriatr Soc*. May 2003;51(5):599-608. PMID 12752833
4. Yokoyama M, Sun X, Oku S, et al. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. *Anesth Analg*. Jun 2004;98(6):1552-1556, table of contents. PMID 15155304
5. 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
6. 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
7. 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
8. 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
9. White PF, Craig WF, Vakharia AS, et al. Percutaneous neuromodulation therapy: does the location of electrical stimulation effect the acute analgesic response? *Anesth Analg*. Oct 2000;91(4):949-954. PMID 11004055
10. Hamza MA, White PF, Craig WF, et al. Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain. *Diabetes Care*. Mar 2000;23(3):365-370. PMID 10868867
11. Ahmed HE, White PF, Craig WF, et al. Use of percutaneous electrical nerve stimulation (PENS) in the short-term management of headache. *Headache*. Apr 2000;40(4):311-315. PMID 10759936
12. Kang RW, Lewis PB, Kramer A, et al. Prospective randomized single-blinded controlled clinical trial of percutaneous neuromodulation pain therapy device versus sham for the osteoarthritic knee: a pilot study. *Orthopedics*. Jun 2007;30(6):439-445. PMID 17598487



13. National Institute for Health and Care Excellence (NICE). Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]. 2013; <https://www.nice.org.uk/guidance/ipg450>. Accessed May 29, 2018.
14. 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
15. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. Oct 2 2007;147(7):478-491. PMID 17909209
16. 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+Nerve+Stimulation&KeywordLookUp=Title&KeywordSearchType=And&list\\_type=ncd&bc=gAAAABAAAA&](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=63&ncdver=2&CoverageSelection=National&Keyword=Electrical+Nerve+Stimulation&KeywordLookUp=Title&KeywordSearchType=And&list_type=ncd&bc=gAAAABAAAA&). Accessed May 29, 2018.
17. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.29 (June 2019).

### Documentation for Clinical Review

- No records required

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.*

#### IE

The following services may be considered investigational.

Type	Code	Description
CPT®	64999	Unlisted procedure, nervous system
HCPCS	None	
ICD-10 Procedure	01HY3MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
07/31/2015	Policy title change from Electrical Stimulation for Pain and Other Conditions Policy revision without position change BCBSA Medical Policy adoption	Medical Policy Committee
03/01/2017	Policy revision without position change	Medical Policy Committee
05/01/2017	Policy revision without position change	Medical Policy Committee
01/01/2018	Coding update	Administrative Review
08/01/2018	Policy revision without position change	Medical Policy Committee
09/01/2019	Policy revision without position change	Medical Policy Committee

## Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*