

POLICY TITLE	PERCUTANEOUS ELECTRICAL NERVE STIMULATION (PENS) AND PERCUTANEOUS NEUROMODULATION THERAPY (PNT)
POLICY NUMBER	MP-6.050

Original Issue Date (Created):	October 25, 2011
Most Recent Review Date (Revised):	November 26, 2013
Effective Date:	February 1, 2014

I. POLICY

Percutaneous electrical neurostimulation or neuromodulation is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

- MP-6.020 Transcutaneous Electrical Nerve Stimulation
- MP- 6.045 Sympathetic Therapy for the Treatment of Pain
- MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
- MP-6.047 Interferential Stimulation for Treatment of Pain
- MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
- MP-6.049 H-Wave Electrical Stimulation
- MP-6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

- | | |
|--------------------------|-----------------|
| [N] Capital Cares 4 Kids | [N] Indemnity |
| [N] PPO | [N] SpecialCare |
| [N] HMO | [N] POS |
| [Y] SeniorBlue HMO* | [Y] FEP PPO** |
| [Y] SeniorBlue PPO* | |

*Percutaneous Electrical Nerve Stimulation (PENS) is a covered service. Refer to Centers for Medicare and Medicaid Services (CMS) National Coverage Determination ([NCD](#)) [160.7.1, 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 Percutaneous Electrical Nerve Stimulation (PENS) when

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used to determine the potential therapeutic usefulness of an electrical nerve stimulator. 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. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

** Refer to FEP Medical Policy Manual MP-7.01.29 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation. The FEP Medical Policy manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

Percutaneous electrical nerve stimulation is a therapy that combines the features of electroacupuncture and transcutaneous electrical nerve stimulation (TENS). PENS therapy uses fine needle-like electrodes that are placed in close proximity to the painful area and stimulate peripheral sensory nerves in the soft tissue.

PENS 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 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 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 electrodes are temporarily placed at specific anatomical landmarks in the deep tissues near the area of the spine that is causing pain (with or without radiating lower extremity pain). Treatment regimens consist of 30-minute sessions, once or twice a week for 8 to 10 sessions.

Regulatory Status

Percutaneous Neuromodulation Therapy™ (Vertis Neurosciences) received approval to market by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2002. The labeled indication reads as follows, “Percutaneous neuromodulation therapy (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

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single-use 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.

IV. RATIONALE

This policy was originally based on a 1996 TEC Assessment of percutaneous electrical nerve stimulation (PENS) for the treatment of chronic pain. (1) 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:

- the study contained original empirical data;
- the study design included a treatment group and a control group;
- the study reported on a health outcome relevant to the pain condition treated; and
- the study used a random assignment, control group design.

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 search covering the period between January 1996 and February 2004. 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, (2) chronic diabetic neuropathy, (3) and chronic headache. (4) 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 transcutaneous electrical nerve stimulation (TENS) or exercise therapy. Patients would undertake 30-minute treatment sessions 3 times per week for 2 or 3 weeks. The order of treatments was random. On completing a treatment, a 1-week washout period would follow, then the patient would proceed to another treatment until all patients had received all treatments. Post-treatment outcome was assessed either immediately after completing the last session of a treatment or up to 3 days later. All 8 studies were conducted at one institution, the University of Texas Southwestern Medical Center in Dallas. The 2004 review showed that evidence was still inadequate to reach conclusions about the effectiveness of PENS for the treatment of chronic pain.

Since 2004, the literature for this policy has been periodically updated using the MEDLINE database. The most recent literature update was performed from July 10, 2012 through June 4, 2013. Following are key studies to date.

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Percutaneous Electrical Nerve Stimulation

Chronic Low Back Pain

In 2008, Weiner and colleagues reported a trial with 200 older adults, which had been funded by the National Institutes of Health. (5) 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 of 2.1 to 3.0 on the Roland scale) and improved gait velocity (0.04 to 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 (NSAID) use, which continued to be present 1 month after treatment completion compared to 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. (6) While PENS treatment for 8 weeks seemed to demonstrate greater effectiveness in controlling pain for up to 1 month after treatment when compared to the other treatment groups, the beneficial effects were not found at the 2-month follow-up.

Ghoname et al. (7) compared sham PENS, active PENS, and TENS in 64 patients. Active PENS achieved better outcomes than sham PENS on visual analogue 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. (8) 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. (9) varied the duration of active electrical stimulation at 3 levels (15, 30, and 45 minutes) and compared them with

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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. (10) 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. (11) 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. (12) 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. (2) 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 side 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., (3) 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-

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week study. Outcome was assessed 1 day after completion of a 3-week treatment period. Active PENS resulted in better outcomes on VAS pain, 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 post-traumatic injury. (4) 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. (13) The pain diagnoses included surgical scar pain, occipital neuralgia, post-traumatic 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 post-herpetic neuralgia. The duration of pain ranged from 1 to 35 years, with a mean of 8.1 years. Subjective pain on a numerical scale and a pressure pain threshold were measured prior to and 1 week after the single treatment, with a washout period of 4 weeks between treatments. The median numerical rating scale 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 gm to 626 gm after active PENS and did not change significantly after sham treatment (202 gm pre, 206 gm 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 numerical rating scale (3.9 vs. 0.1) and in the pain pressure threshold (310 gm vs. 8 gm) for the active compared to 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.

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Percutaneous Neuromodulation Therapy

Chronic Low Back Pain

From its description, percutaneous neuromodulation therapy (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. (14) 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.

A randomized controlled trial (RCT) from 8 U.S. sites was designed to compare Vertis neuromodulation therapy with TENS for chronic low back pain (available online at: www.clinicaltrials.gov: NCT00290238). The study began in 2005, with an estimated enrollment of 122 patients. A posting from May 2009 lists the study as terminated due to slow recruitment and high dropout rates.

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). (15) Patients in the sham group were informed that they would not perceive the normal “pins and needles” with this new device. Patients received one 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 (WOMAC) 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 (e.g., 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 randomized controlled trial was published in 2011 that assessed the efficacy of PNT to control acute pain after TKA. (16) Twice daily PNT or sham treatments were begun following removal of the epidural at 36 to 48 hours post-surgery and

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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 post-treatment). 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 to 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.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 5 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. The input was mixed regarding whether PENS and PNT should be considered investigational or medically necessary.

Summary

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) are therapies that combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. PENS 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. 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 sham (5 minutes of stimulation at 2 needles) treatment. Literature searches have identified only 2 small trials on PNT, and clinical input on the efficacy of PENS and PNT was mixed. The effect of these treatment approaches on health outcomes is uncertain. PENS and PNT are considered investigational.

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Practice Guidelines and Position Statements

The United Kingdom’s National Institute for Health and Care Excellence (NICE) published guidance on PENS in 2013. (17) NICE concluded that the current evidence on the safety of percutaneous electrical nerve stimulation (PENS) for refractory neuropathic pain raises no major safety concerns, that there is evidence of efficacy in the short term and that this procedure may be used with normal arrangements for clinical governance, consent and audit.

The American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation published an evidence-based guideline on the treatment of painful diabetic neuropathy in 2011. (18) The guideline concluded that, based on a Class I study, electrical stimulation is probably effective in lessening the pain of painful diabetic neuropathy and improving quality of life and recommended that PENS be considered for the treatment of painful diabetic neuropathy (level B).

The 2010 Practice guidelines for chronic pain management from the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine state that subcutaneous peripheral nerve stimulation may 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). (19)

Joint clinical practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicate that there is uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture. (20) The guidelines conclude that PENS is not widely available. (The guidelines also conclude that TENS has not been proven effective for chronic low back pain).

Medicare National Policy

The Centers for Medicare and Medicaid Services (CMS) currently has the following national coverage policy on PENS (21):

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,

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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 (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.)”

V. DEFINITIONS

510 (K) refers to A premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

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VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. 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. *White PF, Craig WF, Vakharia AS et al. Percutaneous neuromodulation therapy: does the location of electrical stimulation effect the acute analgesic response? Anesth Analg 2000; 91(4):949-54.*
3. *Hamza MA, White PF, Craig WF et al. Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain. Diabetes Care 2000; 23(3):365-70.*
4. *Ahmed HE, White PF, Craig WF et al. Use of percutaneous electrical nerve stimulation (PENS) in the short-term management of headache. Headache 2000; 40(4):311-5.*
5. *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 2008; 140(2):344-57.*

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6. 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* 2004; 98(6):1552-6, table of contents.
7. Ghoname EA, White PF, Ahmed HE et al. Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica. *Pain* 1999; 83(2):193-9.
8. Ghoname EA, Craig WF, White PF et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. *JAMA* 1999; 281(9):818-23.
9. 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* 1999; 91(6):1622-7.
10. 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* 1999; 88(4):841-6.
11. White PF, Ghoname EA, Ahmed HE et al. The effect of montage on the analgesic response to percutaneous neuromodulation therapy. *Anesth Analg* 2001; 92(2):483-7.
12. 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* 2003; 51(5):599-608.
13. Raphael JH, Raheem TA, Southall JL et al. Randomized double-blind sham-controlled crossover study of short-term effect of percutaneous electrical nerve stimulation in neuropathic pain. *Pain Med* 2011; 12(10):1515-22.
14. Condon JE, Borg-Stein J, Revord J et al. A multicenter trial of percutaneous neuromodulation therapy for low back pain patients with a subacute duration of lower extremity pain. Paper presented at: American Academy of Pain Medicine Annual Meeting 2002; San Francisco, CA.
15. 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* 2007; 30(6):439-45.
16. Wanich T, Gelber J, Rodeo S et al. Percutaneous neuromodulation pain therapy following knee replacement. *J Knee Surg* 2011; 24(3):197-202.
17. National Institute for Health and Care Excellence (NICE). IPG 450. Percutaneous electrical nerve stimulation for refractory neuropathic pain. 2013. Available online at: <http://www.nice.org.uk/nicemedia/live/13961/63356/63356.pdf>. Last accessed June, 2013.
18. Bril V, England J, Franklin GM et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. *Neurology* 2011; 76(20):1758-65.

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19. *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 2010; 112(4):810-33.*
20. *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 2007; 147(7):478-91.*
21. *Centers for Medicare and Medicaid. Medicare Coverage Issues Manual: Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy 160.7.1. 2006. Available online at: http://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=gAAAAABAAAA&. Last accessed July, 2012*

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Percutaneous electrical neurostimulation or neuromodulation is considered investigational; therefore the following code is not covered when billed for percutaneous electrical neurostimulation or neuromodulation:

CPT Codes®							
64999							

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X. POLICY HISTORY

MP-6.050	CAC 10/25/11 Adopted BCBSA. Removed information for PENs from the original policy titled Electrical Stimulation Modalities, and created new separate policy. Changed policy criteria from medically necessary to investigational.
	CAC 10/30/12 Consensus. Changed FEP variation to reference to FEP Medical Policy Manual MP-7.01.29 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation. No change to policy statement. References updated.

MEDICAL POLICY



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	Code reviewed 10/31/12 klr
	CAC 11/26/13 Consensus review. References updated. No changes to the policy statements. Rationale added.

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