

# Regence

Medical Policy Manual

Surgery, Policy No. 44

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

**Effective:** November 1, 2023

**Next Review:** July 2024

**Last Review:** September 2023

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

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

### **MEDICAL POLICY CRITERIA**

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) are considered **investigational** for all indications, including but not limited to treatment of pain.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **POLICY GUIDELINES**

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) vary from other electrical stimulation therapies.

- Transcutaneous electrical nerve stimulation (TENS) delivers impulses across the skin to alleviate pain. PNT and PENS are similar to TENS, except PNT and PENS require electrodes to be inserted into the skin.
- Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation that delivers electrical impulses directly to a nerve. PNS is similar to PNT and PENS, except PNS requires electrodes to be inserted under the skin and targets a nerve considered to be the origin of the pain.
- Peripheral subcutaneous field stimulation (PSFS) is similar to PNT and PENS, except PSFS involves electrical stimulation via electrodes implanted under the skin over the area of maximal pain, whereas PNT and PENS involve inserting fine filaments or needle electrodes through the skin.

## CROSS REFERENCES

1. [Interferential Current Stimulation](#), Durable Medical Equipment, Policy No. 83.07
2. [Electrical Stimulation for the Treatment of Arthritis](#), Durable Medical Equipment, Policy No. 83.10
3. [Transcutaneous Electrical Modulation Pain Reprocessing](#), Medicine, Policy No. 143
4. [Implantable Peripheral Nerve Stimulation and Peripheral Subcutaneous Field Stimulation](#), Surgery, Policy No. 205

## 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, present 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 (TENS) but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area and are then stimulated. PENS is generally reserved for patients who fail to get pain relief from TENS. 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.

### REGULATORY STATUS

Devices which have received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process (FDA product code: NHI) include:

- The Percutaneous Neuromodulation Therapy™ (Vertis Neurosciences) system received approval to market in 2002. The labeled indications for this system are as follows: “Percutaneous neuromodulation therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunct treatment in the management of post-surgical pain and post-trauma pain” (p. 2).<sup>[1]</sup>
- The Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave Corp.) received 510(k) approval in 2006, listing the Vertis Neuromodulation system and a Biowave TENS unit as predicate devices. The Deepwave system was also cleared for marketing for “[s]ymptomatic relief of chronic, intractable pain, postsurgical and post-traumatic acute pain” along with relief of pain following operation or trauma. The system includes a sterile single-use percutaneous electrode array that contains 1014 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.<sup>[2]</sup>
- The Smartpatch® Peripheral Nerve Stimulation (PNS) System (SPR Therapeutics, Inc.) received 510(k) approval in 2016, listing the BiowavePENS System as a predicate device.<sup>[3]</sup> The Smartpatch PNS System is indicated for treatments up to 30 days in the back and/or extremities for symptomatic relief of chronic, intractable pain; post-surgical and post-traumatic acute pain; symptomatic relief of post-traumatic pain; and symptomatic relief of post-operative pain. In 2018, the SPRINT® PNS Systems, *endura*™ and *extensa*™ (SPR Therapeutics, Inc.), were approved for the same indications as the Smartpatch PNS System for up to 60 days.<sup>[4]</sup> In 2021, SPRINT PNS approval was expanded for use in areas of the head, neck, and front of the torso.<sup>[5]</sup> In 2023, indications were expanded to include patients aged 18 and above (previously 21 and above).<sup>[4]</sup>
- In 2021, the First Relief System®, a transcutaneous electrical nerve stimulator device (DyAnsys Inc), received 510(k) approval, listing the SPRINT PNS System as a predicate device.<sup>[6]</sup> First Relief® is indicated for multiple treatments up to 56 days for symptomatic relief of chronic, intractable pain from diabetic peripheral neuropathy. A similar DyAnsys device, Primary Relief®, was approved in 2022 for up to three days for symptomatic relief of post-operative pain following cesarean delivery or up to three days for adjunctive symptomatic relief of post-operative pain following cardiac surgery.<sup>[7]</sup>

## EVIDENCE SUMMARY

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from percutaneous neuromodulation therapy (PNT) or percutaneous electrical nerve stimulation (PENS) provides a significant advantage over placebo.

Treatment with PNT or PENS must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with PNT should be compared to other forms of conservative therapy such as splinting, rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

## PERCUTANEOUS ELECTRICAL NERVE STIMULATION

### Musculoskeletal Pain

#### Systematic Reviews

Rodriguez Lagos (2022) assessed the effects of PENS and transcutaneous electrical nerve stimulation (TENS) on acute and chronic musculoskeletal pain.<sup>[8]</sup> 23 RCTs comparing PENS or TENS with placebo, control group (e.g. sham or no treatment), or standard treatment were included in this systematic review (SR) and meta-analysis. Outcomes included quantitative sensory testing of somatosensory variables such as pressure pain threshold, conditioned pain modulation, and temporal summation of pain. Across all studies, PENS and TENS had a significant effect on pain, with a moderate effect size (standardized mean difference [SMD] 0.53; 95% CI 0.34 to 0.72;  $p < 0.00001$ ). When studies with a high risk of bias were excluded, effects on pain decreased (SMD 0.33; 95% CI 0.7 to 0.58). PENS and TENS did not significantly affect short-term pressure pain thresholds when compared to the control group ( $p = 0.13$ ). PENS and TENS had significant mid-term effects on local pressure pain thresholds (SMD 0.55; 95% CI 0.9 to 1.00,  $p = 0.02$ ) and significant immediate effects on conditioned pain modulation (SMD 0.94; 95% CI 0.48 to 1.41,  $p < 0.0001$ ). The quality of evidence was rated as low or very low for the effects of TENS and PENS on pressure pain thresholds and moderate for effects on conditioned pain modulation. An important bias factor was that no studies were able to blind therapists, and most were unable to blind study participants. The authors concluded that PENS and TENS may have mild-to-moderate immediate effects on local mechanical hyperalgesia in patients with musculoskeletal pain, but additional studies are necessary to draw clearer conclusions.

Beltran-Alacreu (2022) evaluated the effectiveness of PENS compared to (TENS) on the reduction of musculoskeletal pain.<sup>[9]</sup> This systematic SR with meta-analysis included a total of nine RCTs in the qualitative analysis, with seven in the quantitative analysis ( $n = 527$ ). Intervention duration range across studies was two weeks to six months and follow-up time ranged from one week to eight months. The overall effect of PENS on pain was statistically but not clinically superior to TENS (mean difference (MD) = -1.0 cm; 95% confidence interval (CI) -1.5 to -0.4) with a high level of heterogeneity ( $I^2 = 76%$ ,  $p > 0.01$ ). When data only from the three studies with low risk of bias were analyzed, the heterogeneity decreased to  $I = 0%$  ( $p = 0.06$ ) and no difference was observed between TENS and PENS (MD = -0.81 cm; 95% CI -1.6 to 0.02). Six out of the nine studies presented high risk for the blinding of participants, and seven out of nine were high risk for blinding of personnel. Beyond these two items, the risk of bias in the included trials was either low or unclear. Protocols and parameters for the application of PENS and TENS were heterogenous across trials.

Plaza-Manzano (2020) evaluated the effects of PENS alone or as an adjunct to other interventions on pain and related disability in adults with musculoskeletal pain conditions.<sup>[10]</sup> This systematic review with meta-analysis included a total of 19 randomized controlled trials (RCTs). The sample size of included trials ranged from 11 to 121, and the duration of follow-up ranged from less than three months to 10 years. The methodological quality score of the included studies ranged from 3 to 9 out of a total of 10 (mean: 6.3, standard deviation: 1.8). Compared to sham, PENS had a large effect on pain (SMD -1.22, 95% CI -1.66 to -0.79) and a small effect on related disability (SMD -0.33, 95% CI -0.61 to -0.06) at short-term, and compared to other interventions, a moderate effect of PENS alone (SMD -0.71, 95% CI -1.23 to -0.19) on pain was observed. The combination of PENS with other interventions had a

moderate effect on pain at short- (SMD  $-0.70$ , 95% CI  $-1.02$  to  $-0.37$ ) and midterm (SMD  $-0.68$ , 95% CI  $-1.10$  to  $-0.27$ ), however, no effect on related disability was seen at midterm (SMD  $-0.21$ , 95% CI  $-0.52$  to  $0.10$ ). None of the included trials were able to blind therapists. Ten of the trials rated a high risk of bias in the item of allocation concealment and 17 in the item of blinding of participants. Beyond these two items, the risk of bias in the included trials was low. Of note, the quality of included evidence was negatively impacted by the presence of heterogeneity in the data and an insufficient number of participants to meet the desired significance and power in some RCTs. The authors conclude that additional high-quality evidence is needed to determine the clinical effectiveness of PENS for the treatment of musculoskeletal pain.

## **Chronic Low Back Pain**

### Randomized Controlled Trials

Weiner (2008) reported on a RCT with 200 older adults, which was funded by the National Institutes of Health.<sup>[11]</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 six weeks. Thus, the four 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 a brief (five-minute) stimulation from two additional needles. Primary and secondary outcome measures were collected at baseline, one week, and six 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 one-week or six-month follow-up. All four 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 six months. Although the authors found that minimal electrical stimulation (five minutes with two 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 (2003) focused on chronic low back pain in 34 community-dwelling older adults.<sup>[12]</sup> Patients were randomized to twice weekly PENS or sham PENS for six weeks. At three-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>[13]</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 one month after treatment completion compared with a second group that received PENS for four weeks, followed by TENS for four weeks ( $n=17$ ), and a third group that received only TENS for eight weeks ( $n=18$ ). While PENS for eight weeks seemed to demonstrate greater effectiveness in controlling pain for up to one month after treatment compared with the other treatment groups, the beneficial effects were not found at the two-month follow-up.

## **Other Indications**

### Randomized Controlled Trials

Raphael (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>[14]</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 a numeric rating scale (NRS) and a pressure pain threshold were measured before and one week after the single treatment, with a washout period of four 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.

In a crossover study by Hamza (2000), 50 patients with diabetic neuropathic pain for at least six months were randomized to sham PENS or active PENS in a seven-week study.<sup>[15]</sup> Outcomes were assessed one day after completion of a three-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.

Ahmed (2000) conducted a crossover study in 30 patients with longstanding headaches of three types: tension, migraine, and posttraumatic injury.<sup>[16]</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.

### Nonrandomized studies

A study by White (2000) compared two locations of active stimulation with sham stimulation in 68 patients.<sup>[17]</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 three-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.

## **PERCUTANEOUS NEUROMODULATION THERAPY**

### Randomized Controlled Trials

Wanich published results in 2011 from their RCT comparing the Deepwave<sup>®</sup> device with sham treatment among 23 patients following total knee replacement surgery.<sup>[18]</sup> Primary outcomes included reduction in the Visual Analog Scale (VAS) scale of pain, along with reduction in use of opioids. Among the 21 patients who completed the study (two patients in the treatment

group dropped out of the study, citing fatigue from daily treatment), no differences were found in opioid use, although a significant difference was found in average pain reduction favoring the treatment group (19 vs. 25 mm on the 100mmVAS scale,  $p < 0.05$ ), although there was no discussion as to the clinical significance of these results. In addition, application of a per-protocol analysis is likely to have overestimated the treatment benefit where it truly existed, limiting interpretation of results from this study. Larger comparative randomized clinical trials are needed before conclusions can be made about the use of PNT for treatment in pain in total knee replacement surgery or any other indication.

Kang (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>[19]</sup> 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 for one 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.

## PRACTICE GUIDELINE SUMMARY

### American Academy of Neurology

The American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation reaffirmed the 2011 evidence-based guideline on the treatment of painful diabetic neuropathy in 2016.<sup>[20]</sup> The guideline concludes 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 recommend PENS be considered for the treatment of painful diabetic neuropathy (level B, moderate evidence). The guideline was updated in 2022 with a focus on oral and topical treatment of painful diabetic polyneuropathy.<sup>[21]</sup> In the updated guideline, there is no mention of any electrical stimulation strategies for pain.

### 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>[22]</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. These guidelines were updated in 2017 and authors stated that evidence was insufficient to determine harms associated with PENS thus, no recommendation was made.<sup>[23]</sup>

## SUMMARY

There is not enough research to show that percutaneous neuromodulation therapy (PNT) or percutaneous electrical nerve stimulation (PENS) improves health outcomes for people with pain or any other indication. In addition, there are no evidence-based clinical practice guidelines that recommend the use of PNT for the treatment of pain, or any other indication.



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Clinical practice guidelines recommending the use of PENS for the treatment of painful diabetic neuropathy is based on moderate quality of evidence. Therefore, the use of PNT or PENS is considered investigational for all indications including but not limited to treatment of pain.

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## CODES

**NOTE:** There are no specific codes for PENS or PNT. The correct CPT code to use for PENS and PNT is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64561, 64590) are not appropriate since PENS and PNT use percutaneously temporarily inserted needles and wires rather than percutaneously implanted electrodes that are left in place.

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system

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<b>Codes</b>	<b>Number</b>	<b>Description</b>
HCPCS	None	

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*Date of Origin: April 1998*