01.01.35 Non-Implantable Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

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Related Policies:

- 01.01.34 Interferential Current Stimulation
- 01.01.37 Miscellaneous Electrical Stimulation for the Treatment of Pain
- 07.01.78 Implantable Peripheral Nerve Stimulation and Restorative Neurostimulation for the Treatment of Chronic Pain

Summary

Description

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation (TENS).

Percutaneous electrical nerve stimulation is performed with needle electrodes while PNT uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue.

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 and 2 systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and medication use. Two systematic reviews have not revealed consistent benefit from PENS in musculoskeletal pain disorders. One review concluded that PENS could decrease pain intensity but not related disability, while the other found no significant differences between PENS and TENS in mitigation of pain. These conclusions are uncertain due to important methodological limitations in individual trials included in these reviews, such as high heterogeneity with regard to application methods. In the highest quality trial of PENS conducted to date in chronic low back pain, 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 that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions (e.g., knee osteoarthritis) who receive PNT, the evidence consists of a randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, QOL, 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 that the technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of this evidence review is to determine whether treatment with percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy improves the net health outcome in individuals with chronic musculoskeletal or neuropathic pain conditions.

PRIOR APPROVAL

Not applicable.

POLICY

Percutaneous electrical neurostimulation is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Percutaneous neuromodulation therapy is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY GUIDELINES

Coding

See the Codes table for details.

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 QOL.

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.

Percutaneous electrical nerve stimulation 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. Percutaneous electrical nerve stimulation is generally reserved for patients who fail to get pain relief from TENS. Percutaneous electrical nerve stimulation 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.

Percutaneous neuromodulation therapy 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

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 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.

The U.S. Food and Drug Administration (FDA) regulates percutaneous electrical nerve stimulators (PENS) as class II-device under product code NHI (PENS for pain relief), subsequent product code GXZ (electrode needle) and product code BWK (electro-acupuncture stimulator).

RATIONALE

This evidence review was created in October 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 2025.

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 individuals 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 1 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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

Clinical Context and Therapy Purpose

The purpose of percutaneous electrical nerve stimulation (PENS) in individuals who have pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic musculoskeletal or neuropathic pain conditions including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia.

Interventions

The therapy being considered is PENS.

Comparators

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

Outcomes

Specific outcomes of interest for individuals with chronic pain are listed in Table 1. The potential beneficial outcomes of primary interest would be improvements in pain, functioning, and QOL.

Table 1. Outcomes of Interest for Individuals with Chronic Pain

Outcomes	Details
Morbid events	Opioid addiction, adverse events
Health status measures	Pain relief, functional status
Medication use	Number of unsuccessful medication trials, amount of medications needed, dose of medication, dose frequency

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommends that chronic pain trials should consider assessing outcomes representing 6 core domains: pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition. Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.

Table 2. Benchmarks for Interpreting Changes in Chronic Pain Outcome Measures

Outcome Domain and Measure	Type of Improvement	Change
Pain intensity 0 to 10 numeric rating scale	Minimally important Moderately important Substantial	10 to 20% decrease ≥30% decrease ≥50% decrease
Physical functioning Multidimensional Pain Inventory Interference Scale Brief Pain Inventory Interference Scale	Clinically important Minimally important	≥0.6 point decrease 1 point decrease
Emotional functioning Beck Depression Inventory Profile of Mood States Total Mood Disturbance Specific Subscales	Clinically important Clinically important Clinically important	≥5 point decrease ≥10 to 15 point decrease ≥2 to 12 point change
Global Rating of Improvement Patient Global Impression of Change	Minimally important Moderately important Substantial	Minimally improved Much improved Very much improved

Regarding optimal timing of outcome assessment, this varies with pain setting. Per IMMPACT, recommended assessment timing includes at 3, 6, and 12 months in patients with chronic low back pain, 3 to 4 months after rash onset in postherpetic neuralgia, 3 and 6 months in patients with painful chemotherapy-induced peripheral neuropathy, and at various timepoints in the chronic post-surgical pain

setting (i.e., 24 to 48 hours after surgery; 3, 6, and 12 months; or surgery-specific times based on the natural history of acute to chronic pain transition).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Musculoskeletal Pain

Systematic Reviews

Plaza-Manzano et al (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. This systematic review and meta-analysis included a total of 19 RCTs (Table 3). Overall, the results revealed poor quality of evidence (dependent upon the presence of study limitations, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results, and high probability of publication bias), suggesting that PENS alone is associated with a large effect compared with sham and a moderate effect when compared with other interventions for decreasing pain intensity in the short term. Additionally, the combination of PENS with other interventions had a similar poor quality of evidence for a moderate effect for reducing pain intensity than comparative intervention alone. No clear effects of PENS, either alone or in combination, on related disability were seen. 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 2 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.

Beltran-Alacreu et al (2022) evaluated the effectiveness of PENS compared to transcutaneous electrical nerve stimulation (TENS) on the reduction of musculoskeletal pain. This systematic review and meta-analysis included a total of 9 RCTs in the qualitative analysis, with 7 in the quantitative analysis (N=527; Table 3). Overall, there was low-quality evidence for increased pain intensity reduction with PENS over TENS, but the difference found was not deemed to be clinically significant. When only studies with low risk of bias were meta-analyzed, there was a moderate quality of evidence that there is no difference between TENS and PENS for pain intensity. Six out of the 9 studies presented high risk for the blinding of participants, and 7 out of 9 were high risk for blinding of personnel. Beyond these 2 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 all trials. The characteristics and results of both systematic reviews are presented in Tables 4 and 5, respectively.

Table 3. Randomized Controlled Trials Included in the Systematic Review and Meta-Analysis

Study	Plaza-Manzano et al (2020)	Beltran-Alacreu et al (2022)
Ghoname et al (1999)	●	●
Ghoname et al (1999)	●	●
Hamza et al (1999)	●	
Weiner et al (2003)	●	
Topuz et al (2004)	●	●
Yokoyama et al (2004)	●	●
Weiner et al (2008)	●	
Perez-Palomares et al (2010)	●	
Weiner et al (2007)	●	
Weiner et al (2013)	●	
Da Graca Tarrago et al (2016)	●	
Elbadawy et al (2017)	●	
Dunning et al (2018)	●	
Da Graca Tarrago et al (2019)	●	
Leon-Hernandez et al (2016)	●	
Sumen et al (2015)	●	
Medeiros et al (2016)	●	
Botelho et al (2018)	●	
Dunning et al (2018)	●	
Yoshimizu et al (2012)		●
Ng et al (2003)		●
Tsukayama et al (2002)		●
Cheng et al (1987)		●
Lehmann et al (1986)		●

Table 4. Characteristics of the Systematic Review and Meta-Analysis

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Plaza-Manzano et al (2020)	1999-2019	19	Studies that included adults with musculoskeletal pain receiving any type of PENS intervention compared to an acceptable comparator (sham, placebo, control, or another active intervention)	1617 (24-242)	RCT	Intervention duration (sessions/week) varied significantly among the included trials

Beltran-Alacreu et al (2022)	1986-2012	9	Studies that compared TENS vs PENS in adults with musculoskeletal pain	527 (20-131)	RCT	Intervention duration range, 2 weeks to 6 months; follow-up range, 1 week to 8 months

PENS: percutaneous electrical nerve stimulation; RCT: randomized controlled trial; TENS: transcutaneous electrical nerve stimulation.

Table 5. Results of Systematic Review and Meta-Analysis

Study	**Pain intensity (short-term)**			**Pain intensity (mid-term)**	**Related disability (short-term)**	**Related disability (mid-term)**
Plaza-Manzano et al (2020)	PENS alone vs sham	PENS alone vs other intervention	PENS + other intervention vs same intervention alone	PENS alone or in combination vs comparative group	PENS alone or in combination vs comparative group	PENS alone or in combination vs comparative group
N	616	371	730	988	738	568
SMD (95% CI)	-1.22 (-1.66 to -0.79)	-0.71 (-1.23 to -0.19)	-0.70 (-1.02 to -0.37)	-0.68 (-1.10 to -0.27)	-0.33 (-0.61 to -0.06)	-0.21 (-0.52 to 0.10)
I^2 (p)	82% (<.001)	80% (.008)	75% (<.001)	89% (.001)	69% (.02)	71% (.19)
	Pain intensity (post-treatment)		**Pain intensity (follow-up 1 to 8 weeks)**		**Overall pain intensity**	
Beltran-Alacreu et al (2022)	PENS vs TENS	PENS vs TENS (Low risk of bias only)	PENS vs TENS	PENS vs TENS (Low risk of bias only)	PENS vs TENS	PENS vs TENS (Low risk of bias only)
N	405	55	122	8	527	63
MD (95% CI)	-1.21 (-1.92 to -0.5)	-0.82 (-1.77 to 0.13)	-0.57 (-1.06 to -0.08)	-0.80 (-2.60 to 1.0)	-1.0 (-1.55 to -0.45)	-0.81 (-1.6 to 0.02)
p-value	.0008	.09	.02	.38	.0004	.06
I^2 (p)	80% (<.0001)	0% (.68)	0% (.72)	NA	76% (<.00001)	0% (.86)

CI: confidence interval; MD: mean difference; NA: not applicable; PENS: percutaneous electrical nerve stimulation; SMD: standardized mean difference; TENS: transcutaneous electrical nerve stimulation.

Subsection Summary: Musculoskeletal Pain

Two systematic reviews have not revealed consistent benefit from PENS in musculoskeletal pain disorders. One review (19 RCTs, N=1617) concluded that PENS could decrease pain intensity but not related disability, while the other (9 RCTs, N=527) found no significant differences between PENS and TENS in mitigation of pain. These conclusions are uncertain due to important methodological limitations in

individual trials included in these reviews, such as high heterogeneity with regard to application methods. Further well-designed RCTs evaluating the effects of PENS alone or in combination with other interventions is needed, particularly with longer term follow-up.

Chronic Low Back Pain

Randomized Controlled Trials

Weiner et al (2008) reported on an RCT with 200 older adults, which was funded by the National Institutes of Health. Subjects with chronic low back pain were randomized to PENS or sham-control treatment, with or without physical conditioning/aerobic exercise, twice a week for 6 weeks. Thus, the 4 treatment groups were PENS alone, sham PENS alone, PENS plus physical conditioning, or sham PENS plus physical conditioning. The sham-control condition consisted of 10 acupuncture needles in identical locations, depth, and duration (30 minutes) as the PENS needles, with a 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 to 3.0, on the Roland-Morris Disability Questionnaire), and improved gait velocity (0.04 to 0.07 m/s) that was maintained for 6 months. Although trialists concluded that minimal electrical stimulation (5 minutes with 2 needles) was as effective as usual PENS (30 minutes of stimulation with 10 needles), the lack of benefit of this treatment over the sham-control did not support the use of PENS in patients with chronic low back pain.

An earlier study by Weiner et al (2003) focused on chronic low back pain in 34 community-dwelling older adults. Patients were randomized to twice weekly PENS or sham PENS for 6 weeks. At 3-month follow-up, the treatment group reported a significant reduction in pain intensity and disability, while the control group did not. Yokoyama et al (2004) used an active control of TENS in a study with 53 patients.[13,]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 group. One of the reports, by Ghoname et al (1999), compared sham PENS, active PENS, and TENS in 64 patients. Active PENS achieved better outcomes than sham PENS on visual analog scale (VAS) pain scores and daily oral analgesic requirements, and it was better than sham PENS and TENS on physical activity, quality of sleep, and preference. Another report by Ghoname et al (1999) compared sham PENS, active PENS, TENS, and exercise therapy in 60 patients. Active PENS resulted in better outcomes than all other modalities regarding VAS pain, reduction in analgesic requirements, physical activity, quality of sleep, and preference. Hamza et al (1999) varied the duration of active electrical stimulation at 3 levels (15, 30, or 45 minutes) and compared them with sham stimulation in 75 patients. These investigators confirmed that sham PENS had the least effect, and results were best when the stimulation lasted 30 or 45 minutes. Ghoname et al (1999) varied the frequency of the active electrical stimulus, also comparing it with sham stimulation, in 68 patients.[9,] 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

Randomized Controlled Trials

One study by White et al (2000) compared 2 locations of active stimulation with sham stimulation in 68 patients. Local stimulation involved needle insertion at the neck, while remote stimulation entailed needles placed in the lower back. The sham condition received needles with no electrical stimulation at the neck. Outcomes were assessed immediately after completion of a 3-week treatment period. The local placement of active needles resulted in better pain relief, physical activity, quality of sleep, and analgesic use than the local sham treatment or remote active treatment. The study was described as investigator blinded. Withdrawals were not noted, and no long-term outcome data were presented.

Subsection Summary: Chronic Neck Pain

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

Diabetic Neuropathy

Randomized Controlled Trials

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. Racial and ethnic demographics of patients were not described. 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

Randomized Controlled Trials

Ahmed et al (2000) conducted a crossover study in 30 patients with longstanding headaches of 3 types: tension, migraine, and posttraumatic injury. Two-week courses of active and sham PENS were compared. Outcomes were assessed at the completion of each treatment. Active PENS achieved better outcomes

than sham PENS regarding VAS pain, physical activity, and quality of sleep. Results did not vary by headache type. The investigators stated that the study was single-blinded but gave no details about blinding methods or whether withdrawals occurred. The report did not offer long-term outcomes data.

Subsection Summary: Headache

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

Chronic Surface Hyperalgesia

Randomized Controlled Trials

Raphael et al (2011) reported on a multicenter, double-blinded, randomized crossover trial of a single PENS treatment compared with a sham treatment in 30 patients with surface hyperalgesia due to a variety of chronic pain conditions. The pain diagnoses included surgical scar pain, occipital neuralgia, posttraumatic neuropathic pain, stump pain, inflammatory neuropathic pain, chronic low back pain, complex regional pain syndrome, pain following total knee arthroplasty, chronic cervical pain, and postherpetic neuralgia. The duration of pain ranged from 1 to 35 years (mean, 8.1 years). Subjective pain on a numeric rating scale (NRS) and a pressure pain threshold were measured before and 1 week after the single treatment, with a washout period of 4 weeks between treatments. Median NRS scores improved from 7.5 to 0.5 after active PENS and did not change after sham treatment (7.5 pre, 7.5 post). The mean pain pressure threshold improved from 202 to 626 grams after active PENS and did not change significantly after sham treatment (202 grams pre, 206 grams post). Blinding was maintained after the first treatment, but not after the second due to the tingling sensation with active PENS. Analysis of the first treatment showed a significant difference in NRS score change (3.9 vs 0.1) and the pain pressure threshold (310 g vs 8 g) for the active compared with sham treatment.

Section Summary: Percutaneous Electrical Nerve Stimulation

A systematic review concluded that PENS could decrease the level of pain intensity, but not related disability, in musculoskeletal pain disorders. However, the overall level of evidence was low and there was heterogeneity with regard to application methods, leading to the conclusion that there is still high uncertainty regarding the effectiveness of PENS for musculoskeletal pain. The highest quality 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 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 individuals is needed to evaluate the efficacy and confirm clinically meaningful durability of this treatment approach.

Percutaneous Neuromodulation Therapy

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic musculoskeletal or neuropathic pain conditions including knee osteoarthritis.

Interventions

The therapy being considered is PNT.

Comparators

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

Outcomes

Specific outcomes of interest for individuals with chronic pain are listed in Table 1. The potential beneficial outcomes of primary interest would be improvements in pain, functioning, and QOL.

The IMMPACT recommends that chronic pain trials should consider assessing outcomes representing 6 core domains: pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition. Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.

Regarding optimal timing of outcome assessment, this varies with pain setting. Per IMMPACT, recommended assessment timing includes at 3, 6, and 12 months in patients with chronic low back pain, 3 to 4 months after rash onset in postherpetic neuralgia, 3 and 6 months in individuals with painful chemotherapy-induced peripheral neuropathy, and at various timepoints in the chronic post-surgical pain setting (i.e., 24 to 48 hours after surgery; 3, 6, and 12 months; or surgery-specific times based on the natural history of acute to chronic pain transition).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Knee Osteoarthritis

Randomized Controlled Trials

Kang et al (2007) reported on a single-blinded trial that included 70 patients with knee osteoarthritis randomized to stimulation (at the highest tolerable intensity) or placement of electrodes (without stimulation). Patients in the sham group were informed that they would not perceive the normal "pins and needles" with this new device. Patients received 1 treatment and were followed for 1 week. The neuromodulation group had 100% follow-up; 7 (20%) of 35 patients from the sham group dropped out. Visual analog scale pain scores improved immediately after active (from 5.4 to 3.2) but not sham (5.6 to 4.9) treatments. Visual analog scale 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, 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.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine and American Academy of Physical Medicine and Rehabilitation

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. 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). The guidelines were retired and replaced in 2022 with a guideline

dedicated to oral and topical treatment of painful diabetic polyneuropathy. In these updated guidelines, 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. 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.

American Society of Anesthesiologists and American Society of Regional Anesthesia

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).

National Institute for Health and Care Excellence

In 2016 (last updated December 2020) National Institute for Health and Care Excellence (NICE) published guideline on low back pain and sciatica in over 16 years of age: assessment and management that included the following recommendation regarding PENS:

- “Do not offer percutaneous electrical nerve stimulation (PENS) for managing low back pain with or without sciatica.”

In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS. It concluded that the "Current evidence on the safety of [PENS] for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov

REFERENCES

1. Centers for Disease Control and Prevention (CDC). By the Numbers: Diabetes in America. Updated March 2022; https://www.cdc.gov/diabetes/health-equity/diabetes-by-the-numbers.html
2. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. Jan 2005; 113(1-2): 9-19. PMID 15621359

3. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. Feb 2008; 9(2): 105-21. PMID 18055266
4. Gewandter JS, Dworkin RH, Turk DC, et al. Research design considerations for chronic pain prevention clinical trials: IMMPACT recommendations. Pain. Jul 2015; 156(7): 1184-1197. PMID 25887465
5. Plaza-Manzano G, Gómez-Chiguano GF, Cleland JA, et al. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. Eur J Pain. Jul 2020; 24(6): 1023-1044. PMID 32171035
6. Beltran-Alacreu H, Serrano-Muñoz D, Martín-Caro Álvarez D, et al. Percutaneous Versus Transcutaneous Electrical Nerve Stimulation for the Treatment of Musculoskeletal Pain. A Systematic Review and Meta-Analysis. Pain Med. Aug 01 2022; 23(8): 1387-1400. PMID 35167691
7. Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. JAMA. Mar 03 1999; 281(9): 818-23. PMID 10071003
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): 841-6. PMID 10195535
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. Dec 1999; 91(6): 1622-7. PMID 10598602
10. 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
11. Topuz O, Ozfidan E, Ozgen M, Ardic F. Efficacy of transcutaneous electrical nerve stimulation and percutaneous neuromodulation therapy in chronic low back pain. J Back Musculoskeletal Rehabil. 2004;17:127-133.
12. 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. PMID 15155304
13. 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
14. Perez-Palomares S, Olivan-Blazquez B, Magallon-Botaya, et al. Percutaneous electrical nerve stimulation versus dry needling: effectiveness in the treatment of chronic low back pain. J Musculokeletal Pain. 2010;18:23-30
15. Weiner DK, Rudy TE, Morone N, et al. Efficacy of periosteal stimulation therapy for the treatment of osteoarthritis-associated chronic knee pain: an initial controlled clinical trial. J Am Geriatr Soc. Oct 2007; 55(10): 1541-7. PMID 17908057
16. Weiner DK, Moore CG, Morone NE, et al. Efficacy of periosteal stimulation for chronic pain associated with advanced knee osteoarthritis: a randomized, controlled clinical trial. Clin Ther. Nov 2013; 35(11): 1703-20.e5. PMID 24184053
17. da Graca-Tarragó M, Deitos A, Patrícia Brietzke A, et al. Electrical Intramuscular Stimulation in Osteoarthritis Enhances the Inhibitory Systems in Pain Processing at Cortical and Cortical Spinal System. Pain Med. May 01 2016; 17(5): 877-891. PMID 26398594
18. Elbadawy MA. Effectiveness of Periosteal Stimulation Therapy and Home Exercise Program in the Rehabilitation of Patients With Advanced Knee Osteoarthritis. Clin J Pain. Mar 2017; 33(3): 254-263. PMID 27513639
19. Dunning J, Butts R, Henry N, et al. Electrical dry needling as an adjunct to exercise, manual therapy and ultrasound for plantar fasciitis: A multi-center randomized clinical trial. PLoS One. 2018; 13(10): e0205405. PMID 30379937

20. da Graca-Tarragó M, Lech M, Angoleri LDM, et al. Intramuscular electrical stimulus potentiates motor cortex modulation effects on pain and descending inhibitory systems in knee osteoarthritis: a randomized, factorial, sham-controlled study. J Pain Res. 2019; 12: 209-221. PMID 30655690
21. León-Hernández JV, Martín-Pintado-Zugasti A, Frutos LG, et al. Immediate and short-term effects of the combination of dry needling and percutaneous TENS on post-needling soreness in patients with chronic myofascial neck pain. Braz J Phys Ther. Jul 11 2016; 20(5): 422-431. PMID 27410163
22. Sumen A, Sarsan A, Alkan H, et al. Efficacy of low level laser therapy and intramuscular electrical stimulation on myofascial pain syndrome. J Back Musculoskelet Rehabil. 2015; 28(1): 153-8. PMID 25061034
23. Medeiros LF, Caumo W, Dussán-Sarria J, et al. Effect of Deep Intramuscular Stimulation and Transcranial Magnetic Stimulation on Neurophysiological Biomarkers in Chronic Myofascial Pain Syndrome. Pain Med. Jan 2016; 17(1): 122-35. PMID 26408420
24. Botelho L, Angoleri L, Zortea M, et al. Insights About the Neuroplasticity State on the Effect of Intramuscular Electrical Stimulation in Pain and Disability Associated With Chronic Myofascial Pain Syndrome (MPS): A Double-Blind, Randomized, Sham-Controlled Trial. Front Hum Neurosci. 2018; 12: 388. PMID 30459575
25. Dunning J, Butts R, Young I, et al. Periosteal Electrical Dry Needling as an Adjunct to Exercise and Manual Therapy for Knee Osteoarthritis: A Multicenter Randomized Clinical Trial. Clin J Pain. Dec 2018; 34(12): 1149-1158. PMID 29864043
26. Yoshimizu M, Teo AR, Ando M, Kiyohara K, Kawamura T. Relief of chronic shoulder and neck pain by electro-acupuncture and transcutaneous electrical nervous stimulation: A randomized crossover trial. Med Acupunct 2012;24(2):97103.
27. Ng MM, Leung MC, Poon DM. The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation. J Altern Complement Med. Oct 2003; 9(5): 641-9. PMID 14629842
28. Tsukayama H, Yamashita H, Amagai H, et al. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: a preliminary study for a pragmatic trial. Acupunct Med. Dec 2002; 20(4): 175-80. PMID 12512791
29. Cheng RSS, Pomeranz B. Electrotheraphy of chronic musculoskeletal pain: Comparison of electroacupuncture and acupuncture-like transcutaneous electrical nerve stimulation. Cochrane Library. Clin J Pain 1986;2(3):1439.
30. Lehmann TR, Russell DW, Spratt KF, et al. Efficacy of electroacupuncture and TENS in the rehabilitation of chronic low back pain patients. Pain. Sep 1986; 26(3): 277-290. PMID 2946016
31. 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): 193-9. PMID 10534590
32. 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): 949-54. PMID 11004055
33. 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): 365-70. PMID 10868867
34. 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): 311-5. PMID 10759936
35. 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. Oct 2011; 12(10): 1515-22. PMID 21883874
36. 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): 439-45. PMID 17598487

37. 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. May 17 2011; 76(20): 1758-65. PMID 21482920
38. Price R, Smith D, Franklin G, et al. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary: Report of the AAN Guideline Subcommittee. Neurology. Jan 04 2022; 98(1): 31-43. PMID 34965987
39. 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 02 2007; 147(7): 478-91. PMID 17909209
40. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. Apr 04 2017; 166(7): 514-530. PMID 28192789
41. Benzon HT, Connis RT, De Leon-Casasola OA, et al. 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): 810-33. PMID 20124882
42. National Institute for Health and Care Excellence (NICE). Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]. 2013; https://www.nice.org.uk/guidance/ipg45. Accessed August 2025
43. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NICE Guideline NG59 Published November 2016 and last updated December 2020. https://www.nice.org.uk/guidance/ng59. Accessed August 2025
44. UpToDate Management of Diabetic Neuropathy. Topic last updated December 2024. Also available at https://www.uptodate.com
45. UpTodate. Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment. Topic last updated February 2025. Also available at https://www.uptodate.com
46. UpToDate. Approach to the management of chronic non-cancer pain in adults. Topic last updated October 2024. Also available at https://www.uptodate.com
47. UpToDate. Management of nonradicular neck pain in adults. Topic last updated November 2024. Also available at https://www.uptodate.com
48. Hayes, a symplr company Health Technology Assessment Percutaneous Nerve Stimulation for Treatment of Low Back Pain February 2017. Annual Review January 2019
49. UpToDate. Management of Knee Osteoarthritis. Topic last updated July 2025. Also available at https://www.uptodate.com
50. UpToDate. Chronic Migraine. Topic last updated October 2024. Also available at https://www.uptodate.com
51. Hayes, a symplr company Evidence Analysis Research Brief. Percutaneous Electrical Nerve Stimulation for Treatment of Low Back Pain. December 22, 2022

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		

Codes	Number	Description
	64999	Unlisted procedure code, nervous system
HCPCS		
	E1399	Durable medical equipment, miscellaneous
Type of Service	Durable Medical Equipment	
Place of Service	Physician Office, Outpatient	

POLICY HISTORY

Date	Action	Action
August 2025	Annual Review	Policy Revised
August 2024	Annual Review	Policy Renewed
October 2023	Annual Review	Policy Revised – content moved from retired policy “Electrical Stimulation for Treatment of Muscle Rehabilitation, Pain and Miscellaneous Conditions”
August 2022	Annual Review	Policy Revised
December 2021	Interim Review	Policy Revised
August 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
September 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Revised and New Policy Created

Date	Action	Action
January 2013	Annual Review	Policy Renewed
January 2012	Annual Review	Policy Renewed
February 2011	Interim Review	Policy Revised
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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