Medical Policy

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Title: Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Professional / Institutional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia)	Interventions of interest are: • Percutaneous electrical nerve stimulation	Comparators of interest are: • Continued medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use
Individuals: • With chronic pain conditions (e.g., knee osteoarthritis)	Interventions of interest are: • Percutaneous neuromodulation therapy	Comparators of interest are: • Continued medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use

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Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic pain conditions including low back pain	Interventions of interest are: • Restorative neurostimulation therapy (ReActiv8)	Comparators of interest are: • Continued medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use

DESCRIPTION

Percutaneous electrical nerve stimulation (PENS), percutaneous neuromodulation therapy (PNT), and restorative neurostimulation therapy (ReActiv8) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. 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. ReActiv8 is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

OBJECTIVE

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

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.

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.

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Percutaneous neuromodulation therapy is a variant of PENS in which fine filament electrode arrays are place 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.

Restorative neuromodulation therapy (ReActiv8) uses an implanted device to deliver electrical stimulation to the nerves controlling the multifidus muscles of the lumbar spine. It is proposed that restorative neuromodulation reduces pain by triggering contractions of the multifidus muscles to restore neuromuscular control and help stabilize the spine. It is intended for individuals with intractable chronic low back pain associated with multifidus dysfunction for whom available low back pain treatments do not provide sufficient or durable symptom relief.

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.

In 2020, the ReActiv8 (Mainstay Medical) was FDA approved through the Premarket Approval (PMA) process (PMA P190021) for individuals with intractable mechanical chronic low back pain associated with multifidus dysfunction for whom available low back pain treatments do not provide sufficient or durable symptom relief.[1,]

FDA product codes: NHI, QLK.

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POLICY

A. Percutaneous electrical neurostimulation is considered **experimental / investigational.**

B. Percutaneous neuromodulation therapy is considered **experimental / investigational.**

C. Restorative neurostimulation therapy (ReActiv8) is considered **experimental / investigational.**

POLICY GUIDELINES

The correct CPT code to use for percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553 to 64561) are not appropriate, because PENS and PNT use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PENS and PNT are not implanted, so CPT code 64590 is also not appropriate.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through January 22, 2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 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. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

PERCUTANEOUS ELECTRICAL NERVE STIMULATION

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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 quality of life.

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.[2,] Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.[3,]

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

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Outcome Domain and Measure	Type of Improvement	Change
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.[4,] 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 (ie, 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.[5,] 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.

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Beltran-Alacreu et al (2022) evaluated the effectiveness of PENS compared to transcutaneous electrical nerve stimulation (TENS) on the reduction of musculoskeletal pain.[6,] 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/Meta-Analysis

Study	Plaza-Manzano et al (2020)[5,]	Beltran-Alacreu et al (2022)[6,]
Ghoname et al (1999)[7,]	●	●
Ghoname et al (1999)[8,]	●	●
Hamza et al (1999)[9,]	●	
Weiner et al (2003)[10,]	●	
Topuz et al (2004)[11,]	●	●
Yokoyama et al (2004)[12,]	●	●
Weiner et al (2008)[13,]	●	
Perez-Palomares et al (2010)[14,]	●	
Weiner et al (2007)[15,]	●	
Weiner et al (2013)[16,]	●	
Da Graca Tarrago et al (2016)[17,]	●	
Elbadawy et al (2017)[18,]	●	
Dunning et al (2018)[19,]	●	
Da Graca Tarrago et al (2019)[20,]	●	
Leon-Hernandez et al (2016)[21,]	●	
Sumen et al (2015)[22,]	●	
Medeiros et al (2016)[23,]	●	
Botelho et al (2018)[24,]	●	
Dunning et al (2018)[25,]	●	

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Study	Plaza-Manzano et al (2020)[5,]	Beltran-Alacreu et al (2022)[6,]
Yoshimizu et al (2012)[26,]		●
Ng et al (2003)[27,]		●
Tsukayama et al (2002)[28,]		●
Cheng et al (1987)[29,]		●
Lehmann et al (1986)[30,]		●

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

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Plaza-Manzano et al (2020)[5,]	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)[6,]	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 the Systematic Review/Meta-Analysis

Study	Pain intensity (short-term)			Pain intensity (mid-term)	Related disability (short-term)	Related disability (mid-term)
Plaza-Manzano et al (2020)[5,]	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)

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	Pain intensity (post-treatment)		Pain intensity (follow-up 1 to 8 weeks)		Overall pain intensity	
Beltran-Alacreu et al (2022)[6,]	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.[13,] 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.

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An earlier study by Weiner et al (2003) focused on chronic low back pain in 34 community-dwelling older adults.[10,] 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.[12,]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.[31,] 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.[7,] 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.[9,] 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.[8,] 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.[32,] 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

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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.[33,] 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.[34,] 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.[35,] 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

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change after sham treatment (7.5 pre, 7.5 post). The mean pain pressure threshold improved from 202 to 626 grams after active PENS and did not change significantly after sham treatment (202 grams pre, 206 grams post). Blinding was maintained after the first treatment, but not after the second due to the tingling sensation with active PENS. Analysis of the first treatment showed a significant difference in NRS score change (3.9 vs 0.1) and the pain pressure threshold (310 g vs 8 g) for the active compared with sham treatment.

Subsection Summary: Chronic Surface Hyperalgesia
A single study has reported positive effects on PENS for chronic surface hyperalgesia. Longer term follow-up in a larger sample is needed to evaluate the efficacy and confirm clinically meaningful durability of this treatment approach.

Section Summary: Percutaneous Electrical Nerve Stimulation
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.

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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 quality of life.

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.[2,] Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.[3,]

Regarding optimal timing of outcome assessment, this varies with pain setting.[4,] 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 (ie, 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).[36,] 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

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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.

RESTORATIVE NEUROSTIMULATION THERAPY

Clinical Context and Therapy Purpose

The purpose of restorative neurostimulation therapy in individuals with chronic pain conditions 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.

Interventions

The therapy being considered is restorative neurostimulation therapy. The ReActiv8 System is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

Comparators

The following practice is currently being used: continued medical management.

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 quality of life.

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.[2,] Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.[3,]

Regarding optimal timing of outcome assessment, this varies with pain setting.[4,] Per IMMPACT, recommended assessment timing includes at 3, 6, and 12 months in individuals with chronic low back pain.

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.

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REVIEW OF EVIDENCE

Systematic Reviews

Bess et al (2025) identified 6 prospective studies (N=650; 2 RCTs [see below]) evaluating restorative neurostimulation in patients with multifidus dysfunction and chronic low back pain.[37,] At 1 year, restorative neurostimulation reduced NRS by a mean of 3.2 points, Oswestry Disability Index (ODI) by 16.8 points, and an improvement in health-related quality of life (EQ-5D) of 0.200. At 4 years, there was a weighted average reduction in NRS pain of 4.1, a 22.7 point reduction in ODI, and an EQ- 5D improvement of 0.251. The only trial with an active comparator was the RESTORE trial (see Schwab et al 2025 below) which had NRS reduction of 0.5, ODI improvement of 2.9, and EQ-5D improvement of 0.013 at 1 year.

Randomized Controlled Trials

Restorative neurostimulation therapy with the ReActiv8 system has been evaluated in a multicenter, sham-controlled RCT enrolling 204 individuals with chronic, refractory low back pain (ReActiv8-B, NCT02577354). Study characteristics are summarized in Table 6. Control group participants received treatment with the ReActiv8 system set to deliver low-level stimulation. The primary endpoint was the difference in proportions of responders in the treatment and control groups. Response was defined as the composite of 30% or greater reduction in VAS and no increase in pain medications, assessed at 120 days. Following the 120-day randomized phase, participants in the control group were given the option to cross over to the intervention group and were followed along with the participants from the intervention group for up to 3 years. Primary study results were reported by Gilligan et al (2021).[38,] Information on the RCT is also included in the FDA Summary of Safety and Effectiveness Data conducted as part of the premarket approval process.[39,] At 120 days, there was no difference between groups on the primary endpoint of treatment response (57.1% intervention vs 46.6% sham; p =.1377) or the individual components of the primary endpoint (see Table 7). The study investigators conducted prespecified secondary analyses of the primary outcome data, including the between-group difference in VAS at 120 days, a review of participants with increased pain medications, and a cumulative-proportion-of-responders analysis, which graphically displays the proportion of responders across the range of all possible cutoffs and is described as having greater statistical power than the comparison of proportions of the dichotomized primary outcome. The VAS mean change from baseline to 120 days favored the intervention group (-3.3 vs -2.4; p =.032), but it is unclear if the difference between groups (0.9 points) was clinically meaningful. The cumulative proportion-of-responders analysis similarly favored the intervention group (p =.0499). Nine participants in both the intervention and control groups had an increase in pain medication at 120 days, but the increase was unrelated to low back pain in 6 of 9 participants in the treatment group versus 0 of 9 in the control group. Study limitations are summarized in Tables 8 and 9. Most importantly, the controlled phase was only 120 days. In the longer-term, uncontrolled follow-up phase of the trial, there was continued improvement in VAS scores over time in those who were assessed, but the lack of a control group and high attrition limits drawing conclusions from these results. Data was available for 176 of 204 participants at 1 year (86.3%),[38,] 156 of 204 participants (79%) at 2 years,[40,] and 130 of 204 (63.7%) at 3 years.[41,]Gilligan et al (2024) reported follow-up at 5 years.[42,] A total of 126 patients were included and back pain VAS improved from 7.3 at baseline to 2.3 at 5-year follow-up with 71.8% of participants reporting a reduction of at least 50%. ODI scores and EQ-5D scores were also improved at long-term follow-up.

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Schwab et al (2025) conducted a multicenter, open-label RCT investigating the effect of restorative neurostimulation therapy using the ReActiv8 system compared to optimal medical management (OMM) for treating chronic low back pain (CLBP) due to multifidus dysfunction (N=203) (RESTORE, NCT04803214).[43,] Participants were randomized to either restorative neurostimulation (n=99) or OMM (n=104). The primary endpoint was the mean change in the ODI at 1 year. Study characteristics and primary results are summarized in Tables 6 and 7. The results showed a significant improvement in ODI for the treatment arm compared to the control arm (ODI: 19.7 ± 1.4 vs. 2.9 ± 1.4; p<.001). Secondary endpoints also showed significant improvements in the numeric rating scale (NRS) in the treatment arm compared to the control arm for pain (3.6 ± 0.2 vs. 0.6 ± 0.2; p<.001) and health-related quality of life (EQ-5D-5L) (0.155 ± 0.012 vs. 0.008 ± 0.012; p<.001). 72% of patients in the treatment arm reached the composite endpoint of ≥ 15-point ODI improvement and/or ≥50% NRS improvement, compared to 11% in the control arm (p<.001). Safety outcomes indicated that 31 device-, procedure-, and/or therapy-related adverse events occurred in 23 (23.2%) patients in the treatment arm, with common events including implant site pocket pain (8.1%), device overstimulation (5.1%), and lead fracture (3.0%). Study limitations are summarized in Tables 8 and 9. Several limitations were identified. Participants were not blinded which could have led to placebo effects in the treatment arm and nocebo effects in the control arm. The treatment arm received more clinical contact than standard management protocols for restorative neurostimulation therapy which could artificially inflate healthcare utilization in the short term. There was a statistically significant imbalance in baseline depression with more active depression in the control arm than the treatment arm which could bias the effectiveness of treatment. Changes in medication were collected but not reported in the published analysis.

Smuck et al (2025) conducted a post-hoc reanalysis of the sham-controlled pivotal trial (ReActiv8-B, N=204) to evaluate categorical responder rates using common clinically relevant improvement thresholds that were not included in the original trial's analysis plan.[44,] Using a complete-case analysis (n=201 at 120 days), the reanalysis reported statistically significant differences favoring treatment over sham for ODI improvement at the ≥15-point threshold (59.0% vs 40.6%; p=.0111) and ≥30% threshold (65.0% vs 47.5%; p=.0156), EQ-5D improvement at the ≥0.15-point threshold (57.0% vs 36.0%; p=.0045), and subject global impression of change of "better" or more (54.0% vs 33.7%; p=.0045). However, categorical pain responder rates on VAS did not differ significantly at the ≥2-point threshold (61.0% vs 49.5%; p=.1192) or ≥50% improvement threshold (45.0% vs 35.6%; p=.1971), although mean VAS change favored treatment (−3.3 vs −2.4; p=.0209). This study has limitations. As a post-hoc reanalysis, the outcome thresholds reported were not included in the original trial's prespecified statistical analysis plan, introducing the potential for selective reporting bias. The reanalysis used a complete-case analysis that modified the population handling of the original intention-to-treat analysis, including all participants without regard to the pain medication log criterion used in the original primary endpoint. Additionally, the 120-day follow-up may not capture the full treatment effect, and these results do not provide information regarding longer-term outcomes.

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Table 6. Randomized Controlled Trial of Restorative Neurostimulation Therapy (ReActiv8) for Chronic Low Back Pain: Study Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Gilligan et al (2021)[38,] NCT02577354	US, Australia	26	2016-2018	N = 204 Age 22 to 75 years with nonneuropathic mechanical chronic LBP with pain on at least half of the days in the prior year, and continuing LBP despite 90 days of medical management; positive prone instability test suggesting impaired motor control of the multifidus muscle and consequent lumbar segmental instability	Restorative neurostimulation therapy with the ReActiv8 System programmed to a patient appropriate stimulation level	Active sham (ReActiv8 programmed to deliver low level stimulation)
Schwab et al (2025)[43,] NCT04803214	US	25	2021-2023	N=203 Ages 21 to 74 years with moderate to severe pain and disability associated with CLBP persisting for longer than 6 months (NRS: 6 to 9 and ODI: 30 to 60) and had failed previous treatments, including pain medications and physical therapy; all participants had evidence of lumbar multifidus muscle dysfunction, confirmed by physical assessment or MRI imaging	Restorative neurostimulation therapy with the ReActiv8 system	Optimal medical management treatment plan that was established prior to randomization

CLBP: chronic low back pain; LBP: low back pain; MRI, magnetic resonance imaging; NRS, numeric rating scale; ODI, Oswestry Disability Index.

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Table 7. Randomized Controlled Trial of Restorative Neurostimulation Therapy (ReActiv8) for Chronic Low Back Pain: Results

Study	Primary Outcome:Response (> 30% reduction in VAS and no increase in pain medications at day 120)	VAS Response at day 120 (component of primary endpoint)	Increase in pain medication at 120-day visit (component of primary endpoint)	Mean Change in VAS at day 120 (SD)	Primary Outcome: Change in ODI at 1 year, mean ± SE
Gilligan et al (2021)[38], NCT02577354	204	102	201	201	
ReActiv8	57.1%	58.8%	9 (6 unrelated to LBP)	-3.3 (2.7)	
Sham Control	46.6%	48.6%	9 (0 unrelated to LBP)	-2.4 (2.9)	
Difference (95% CI)	10.4% (-3.3% to 24.1%)			0.9	
p-value	.1377	.1438	NA	.032	
Schwab et al (2025)[43], NCT04803214					203
ReActiv8 (n=99)					-19.7 ± 1.4
OMM (n=104)					-2.9 ± 1.4
Difference (95% CI)					-16.8 ± 1.9 (-20.6 to -13.0)
p-value					<.001

CI: confidence interval; LBP: low back pain; NA: not applicable; ODI, Oswestry Disability Index; OMM, optimal medical management; SD: standard deviation; SE, standard error; VAS: visual analog scale.

Table 8. Randomized Controlled Trial of Restorative Neurostimulation Therapy (ReActiv8) for Chronic Low Back Pain: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Gilligan et al (2021)[38], NCT02577354	4. Race/ethnicity of participants not reported				1. Follow-up was 120 days in controlled phase
Schwab et al (2025)[43],	5. Statistically significant imbalance in	5. Greater clinical contact than standard	2. Not sham-controlled		

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Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
NCT04803214	baseline depression between treatment and control arms	management protocols in the treatment arm			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 9. Randomized Controlled Trial of Restorative Neurostimulation Therapy (ReActiv8) for Chronic Low Back Pain: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Gilligan et al (2021)[38,] NCT02577354				1. high attrition in longer-term, uncontrolled phase		
Schwab et al (2025)[43,] NCT04803214		1. Participants and study staff not blinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

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Nonrandomized Studies

Nonrandomized studies of restorative neurostimulation therapy for chronic low back pain are at high risk of bias due to lack of blinding, small sample sizes, high attrition, and no sham control, but are briefly discussed here for completeness. A prospective single-arm trial (ReActiv8-A; NCT01985230) was conducted at 9 sites in the United Kingdom, Belgium, and Australia to assess technical feasibility, performance, and safety of the ReActiv8 system. Participants were followed at 45, 90, 180, and 270 days, then annually for 4 years. Results at 1 year,[45,] 2 years,[46,] and 4 years[47,] have been published. Of 53 participants enrolled, 33 completed 4-year follow-up. Of these, 73% had a clinically meaningful improvement of 2 points or greater on the low back pain Numeric Rating Scale and 76% had an improvement of 10 points or greater on the Oswestry Disability Scale.[47,] A case series (N=44) published in 2022 reported the experience of a single surgeon in Germany.[48,] After 1 year of therapy, 68% of individuals with refractory chronic low back pain who received treatment with the Reactive8 device had moderate (30% or greater) reductions in pain and 52% had substantial (greater than 50%) reductions in pain.

Section Summary: Restorative Neurostimulation Therapy

The evidence includes a systematic review, 1 sham-controlled RCT (N=204), 1 open-label RCT (N=203), 1 prospective single-arm trial (N=53), and a case series (N=44). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In the sham-controlled RCT, there was no difference between groups on the primary endpoint of treatment response at 120 days, defined as the composite of 30% or greater reduction in VAS and no increase in pain medications (57.1% intervention vs 46.6% sham; p=.1377). Prespecified secondary analyses of primary outcome data favored the intervention group, but clinical significance is unclear. An uncontrolled follow-up phase of the RCT reported continued improvement in pain scores through 5 years but results are at high risk of bias due to lack of a control group and high attrition. The open-label RCT showed statistically significant improvements in the treatment arm compared to the control arm in the primary and secondary outcomes. However, limitations included lack of blinding, imbalance in baseline depression between treatment and control arms, and greater clinical contact than standard management protocols in the treatment arm. Nonrandomized studies are limited by lack of blinding, no sham control, high attrition, and small sample sizes. Additional evidence from longer-term sham-controlled RCTs is needed.

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 et al

The American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation reaffirmed 2011 evidence-based guidelines on the treatment of painful diabetic neuropathy in

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2016.[49,] 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.[50,] 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.[51,] 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.[52,]

American Society of Anesthesiologists et al

The 2010 practice guidelines for chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine indicated that subcutaneous peripheral nerve stimulation might be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies (category B2 evidence, observational studies).[53,]

American Society of Interventional Pain Physicians

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published guidelines on the use of peripheral nerve stimulation systems (eg, ReActiv8) for the treatments of moderate to severe chronic refractory pain.[54,] Table 10 includes relevant recommendations from these guidelines.

Table 10. ASIPP Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	SOR
The evidence of effectiveness of peripheral nerve stimulation in managing chronic pain, based on evidence synthesis utilizing comprehensive and systematic review of the literature with methodologic quality assessment of all studies, applying GRADE criteria, and best evidence synthesis for implantable peripheral nerve stimulation systems following a trial or selective lumbar medial branch stimulation without a trial, is Level III or fair with moderate certainty utilizing GRADE criteria.	Fair	Moderate
The evidence of effectiveness of peripheral nerve stimulation in managing chronic pain based on evidence synthesis utilizing comprehensive and systematic review of the literature with methodologic quality assessment of all studies, applying GRADE criteria, and best evidence synthesis for implantable stimulation systems following temporary peripheral nerve stimulation for 60 days is Level III or fair with moderate certainty utilizing GRADE criteria.	Fair	Moderate
Based on the evidence and the recommendations, indications may be expanded from present CMS guidance with addition of craniofacial pain, phantom limb pain, and low back pain, either nociceptive or neuropathic, with present evidence showing Level III or fair with moderate certainty utilizing GRADE criteria.	Fair	Moderate

LOE: level of evidence; SOR: strength of recommendation

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American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience (ASPN) published consensus clinical guidelines for the use of implantable peripheral nerve stimulation (eg, ReActiv8) in the treatment of chronic pain based on a review of the literature through March 2021.[55,] Relevant recommendations for best practices pertinent to this review are listed below in Table 11.

Table 11. American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	DOR
Upper Extremities		
PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain.	I	B
PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief.	II-2	B
Lower Extremities		
PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief.	I	B
PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief.	I	B

DOR: degree of recommendation; LOE: level of evidence; PNS: peripheral nerve stimulation.

National Institute for Health and Care Excellence

In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS.[56,] 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."

In September 2022, NICE published guidance on neurostimulation of lumbar muscles with the ReActiv8 system for refractory non-specific chronic low back pain.[57,]

The guidance was based on a rapid review conducted in July 2021 and included the following statements:

- "Evidence on the efficacy and safety of neurostimulation of lumbar muscles for refractory non-specific chronic low back pain is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."
- "Further research should include suitably powered randomised controlled trials comparing the procedure with current best practice with appropriate duration. It should report details of patient selection and long-term outcomes."
-

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT07273006	Percutaneous Electrical Nerve Stimulation As Alternative To Nerve Blocks In Anesthesia, Pain Medicine And Rehabilitation Of Nonspecific Chronic Pain	82	Aug 2029
NCT04243915	Effectiveness of Percutaneous Neuromuscular Electrical Stimulation on Lumbar Multifidus in Combination With a Protocol of Motor Control Exercises in Patients With Chronic Low Back Pain	64	Dec 2024 (unknown status)
Unpublished			
NCT04442321	Effectiveness of Ultrasound-Guided Percutaneous Electrical Stimulation on Radial Nerve With Exercises in Patients With Lateral Epicondylalgia	60	Dec 2024 (actual)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
64999	Unlisted procedure, nervous system
1088T	Percutaneous application of high-frequency neuromodulation signals using microneedle electrode array for the treatment of nociceptive or neuropathic pain, including electrode placement and patient training, per day

REVISIONS	
Posted 08-22-2023 Effective 09-21-2023	Policy added to the bcbsks.com web site.
07-23-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
08-12-2025	Updated Description Section
	Updated Rationale Section
	Updated References Section
01-01-2026	Updated Coding Section ▪ Added new code C1607 (eff. 01-01-2026)
05-14-2026	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed C1607
	Updated References Section
10-01-2026	Updated Coding Section ▪ Added New Code 1088T (eff. 10-01-2026)

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