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***Current Policy Effective Date: 7/1/25**
(See policy history boxes for previous effective dates)

Title: Implantable Peripheral Nerve Stimulation and Peripheral Subcutaneous Field Stimulation Devices for the Treatment of Chronic Pain

Description/Background

Peripheral Nerve Stimulation
Peripheral nerve stimulation (PNS), or percutaneous peripheral nerve stimulation, involves the implantation of electrodes near or on a peripheral nerve that is identified as transmitting pain to a specific area of the body. This is proposed for the treatment of chronic, refractory pain that is nonresponsive to conservative treatments.

Peripheral Subcutaneous Field Stimulation (Peripheral Nerve Field Stimulation-PNFS)
Peripheral subcutaneous field stimulation (PSFS) is a modification of peripheral nerve stimulation. In PSFS, leads are placed subcutaneously within the area of maximal pain. The objective of PSFS is to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, which then converge back on the spinal cord. Combined spinal cord stimulation plus PSFS is also being evaluated.

Similar to spinal cord stimulation or peripheral nerve stimulation, permanent implantation is preceded by a trial of percutaneous stimulation with at least 50% pain reduction. Currently, there is no consensus on the indications for peripheral subcutaneous field stimulation. Criteria for a trial of peripheral subcutaneous field stimulation may include a clearly defined, discrete focal area of pain with a neuropathic or combined somatic/neuropathic pain component with characteristics of burning and increased sensitivity, and failure to respond to other conservative treatments including medications, psychological therapies, physical therapies, surgery, and pain management programs.

The mechanism of action in PNS and PSFS is unknown. Theories include an increase in endogenous endorphins and other opiate-like substances, modulation of smaller A delta and C fibers by stimulated large-diameter A beta fibers; local stimulation of nerve endings in the skin; local anti-inflammatory and membrane depolarizing effect; or a central action via antegrade activation of A beta nerve fibers. Complications of PNS/PSFS include lead migration or breakage and infection of the lead or neurostimulator.

CHRONIC PAIN

Chronic, noncancer pain is responsible for a high burden of illness. Common types of chronic pain are lumbar and cervical back pain, chronic headaches, and abdominal pain. All of these conditions can be challenging to treat.

Treatment

Pharmacologic agents are typically the first-line treatment for chronic pain, and several classes of medications are available. They include analgesics (opioid and nonopioid), antidepressants, anticonvulsants, and muscle relaxants. A variety of nonpharmacologic treatments also exist, including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, and chiropractic and therapeutic massage.

Neuromodulation, a form of nonpharmacologic therapy, is usually targeted toward patients with chronic pain refractory to other modalities. Some forms of neuromodulation, such as transcutaneous electrical nerve stimulation (TENS) and spinal cord stimulation, are established methods of chronic pain treatment. Peripheral nerve stimulation, which involves placement of an electrical stimulator on a peripheral nerve, is also used for neuropathic pain originating from peripheral nerves.

Regulatory Status

A number of PSFS and PNS devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These are listed in Table 1.

Two PNS devices by Stimwave Technologies Inc., the StimQ Peripheral Nerve Stimulator (PNS) System and the Receiver Kit, Trial Kit, Spare Lead Kit, Sterile Revision Kit, SWAG Kit, SWAG Accessory Kit, Charger Kit, were recalled in Sept 2020 for the product containing a non-functional component not referenced in product labeling.

Table 1. FDA Cleared PNS Devices

Device Name	Manufacturer	Cleared	510(k)	Indications
SPRINT® Peripheral Nerve Stimulation System	SPR Therapeutics, Inc	July 2018	K181422	The FDA determined that this device was equivalent to existing devices for use in pain management. Peripheral subcutaneous field stimulation is also an off-label use of spinal cord stimulation devices that have been approved by the FDA for the treatment of chronic pain.

Nalu Neurostimulation Kit (Integrated, 40 cm: Single 8/Dual 8), Nalu Neurostimulation Kit (Ported, 2 cm: Single 8/Dual 8), Dual 8 Ported Nalu Implantable Pulse Generator with 40 cm Kit, 40 cm/ 60 cm Trial/Extension Lead Kits, Patient Kits and miscellaneous replacement kits	Nalu Medical, Inc.	March 2019	K183579	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
IPG, integrated, 25/40 cm, single, tined, IPG, 2 cm, single 4, Lead (25/40 cm, 4, tined), Extension - 4	Nalu Medical, Inc.	Sept 2019	K191435	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
StimRouter Neuromodulation System	Bioness, Inc.	Oct 2019, March 2020, Feb 2022	K190047, K200482, K211965	The StimRouter Neuromodualtion System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (eg, medications). The StimRouter is not intended to treat pain in the craniofacial region.
Stimulator, Stimulator Kit, External Transmitter, External Transmitter Kit	Micron Medical Corporation	Aug 2020	K200848	Moventis PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Moventis PNS is not intended to treat pain in the craniofacial region.
Neuspera Neurostimulation System (NNS)	Neuspera Medical, Inc.	Aug 2021	K202781	The Neuspera Neurostimulation System (NNS) is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
Neuspera Nuity System	Neuspera Medical, Inc.	April 2023	K221303	The Neuspera Nuity™ System (NNS) is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.

Medical Policy Statement

Implantable peripheral nerve stimulation (PNS) devices for the treatment of chronic pain are experimental/investigational. There is insufficient evidence to demonstrate improvement in net health outcomes.

Implantable peripheral subcutaneous field stimulation (PSFS) devices for the treatment of chronic pain are experimental/investigational. There is insufficient evidence to demonstrate improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

64999 64555 64596 64597 64598

Rationale

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, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less

common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Implantable Peripheral Nerve Stimulation

Clinical Context and Therapy Purpose
The purpose of implantable PNS in individuals who have peripheral neuropathic chronic 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(s) of interest are individuals with peripheral neuropathic chronic pain which may be caused by damage to peripheral nerves impacting the upper and lower extremities that is persistent for longer than 3 months. This population does not include individuals with chronic pain such as craniofacial, migraine, low back and trunk, amputation, or post-traumatic pain.

Interventions
The therapy being considered is implantable PNS. It is an implantable system consisting of leads, electrodes, and a pulse transmitter that delivers electrical impulses to peripheral nerves. Leads are placed using ultrasound guidance and can be placed for temporary or permanent use in an outpatient procedure.

Comparators
The following therapies are currently being used to make decisions about implantable PNS: pharmacologic and nonpharmacologic treatments.

Outcomes
The general outcomes of interest are symptoms, medication use, and quality of life.
As a chronic condition, follow-up of at least 6 weeks to 12 months would be desirable to assess outcomes in chronic neuropathic pain.

Review of Evidence
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.[8] Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.[9]

Table 2. Health Outcome Measures Relevant to Individuals with Chronic Pain

Outcome	Measure (Units)	Description	Thresholds for Improvement/Decline or Clinically Meaningful Difference (If Known)

Pain intensity	0 to 10 numeric rating scale	Patient reported rating of pain intensity.	Minimally important (10 to20% decrease) Moderately important (≥30%decrease) Substantial (≥50% decrease)
Physical functioning	Multidimensional Pain Inventory Interference Scale	A 60-item self-report inventory of patients' cognitive, behavioral, and affective responses to their condition. Decreasing score indicates improvement.	Clinically important (≥0.6 point decrease)
	Brief Pain Inventory Interference Scale	A 7-item self-report assessment of pain interference with physical and emotional functioning and sleep. Decreasing score indicates improvement.	Minimally important (1 point decrease)
Emotional functioning	Beck Depression Inventory (score)	Assessment of depression severity ranging from 0 to 63. Decreasing score indicates improvement.	Clinically important (≥5 point decrease)
Profile of Mood States	Total Mood Disturbance (score)	A 65-item checklist of mood disturbances with 6 subscale scores. Decreasing score indicates improvement.	Clinically important (≥10 to 15point decrease)
	Specific Subscales (score)		Clinically important (≥2 to 12point change)
Global Rating of Improvement	Patient Global Impression of Change (rating)	A single-item rating by participants of their response to treatment in a clinical trial using a 7-point rating scale, ranging from "very much improved" to "very much worse."	Minimally important: "minimally improved "Moderately important: "much improved "Substantial: "very much improved"

Systematic Reviews

A systematic review has been published.[10] The only relevant RCT from the systematic review is discussed in the following section and the systematic review will not be discussed further here.

Randomized Controlled Trials

Deer et al (2016) conducted an RCT to assess the safety and efficacy of PNS using the StimRouter Neuromodulation System to treat individuals with chronic pain of peripheral nerve origin.[11] Participants (N=94) were randomized 1:1 into the treatment (n=45) or control (n=49)

group. The treatment group received PNS and a stable dose of pain medications, and the control group received no PNS and a stable dose of pain medications for 90 days. After 90 days, crossover from the control group to the treatment group was offered. Study visits were planned at 30, 60, and 90 days after randomization, with follow-up at 6 and 12 months. The primary outcomes were pain relief and safety. Average pain at rest was measured by a numerical rating scale (NRS) over 3 months and safety was assessed by adverse events reported during the 1-year study period. A responder was defined as having at least a 30% decrease in the NRS with no upward titration in pain medications. Secondary outcomes included changes in medication, quality of life, patient global impression of change scale (PGIC), and change in worst pain using the NRS. At 90 days, there was a statistically significant difference between the treatment group and control group in the mean reduction in average pain from baseline (27.2% vs. 2.3%; p<.0001). There were statistically significantly more responders in the treatment group compared to the control group (38% vs. 10%; p=.0048). At 90 days, the treatment group compared to the control group had a significantly better improvement in quality of life (change from baseline [mean ± SD]: 1.4 ±5.9 vs. -0.2 ± 3.4; p=.037) and PGIC (mean ± SD: 4.8 ± 1.5 vs. 2.5 ± 1.9; p<.0001). There was no device related serious adverse events through follow-up (mean duration: 320 days). Study characteristics and results are summarized in Tables 3 and 4. Study limitations are summarized in Tables 5 and 6.

Table 3. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
Deer et al (2016)	US	13	NR	Individuals with chronic pain of peripheral nerve origin.	PNS and a stable dose of pain medications for 90 days with up to 12month follow-up. (n=45)	No PNS and a stable dose of pain medications for 90 days, then option to crossover to treatment with up to 12-month follow-up. (n=49)

NR: not reported; RCT: randomized controlled trial

Table 4. Summary of Key RCT Results

Study	Mean Pain Reduction from Baseline (%)	Responders (%)	Pain Medication Increased, N (%)	Quality of Life, mean ± SD			PGIC, mean ± SD
	3 Months	3 Months	3 Months	Baseline	3 Months	Change	3 Months
Deer et al (2016)	N=94	N=94	N=94	N=94	N=94	N=94	N=94
Treatment (n=45)	27.2	38	1 (2.2%)	35.5 ± 4.9	36.9 ±4.5	1.4 ± 5.9	4.8 ± 1.5

Control (n=49)	2.3	10	2 (4.1%)	36.0 ± 4.3	35.8 ±4.3	-0.2 ±3.4	2.5 ± 1.9
p-value	<.0001	.0048	NR	.389	.250	.037	<.0001

PGIC: patient global impression of change; RCT: randomized controlled trial; SD: standard deviation.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Deer et al (2016)	1. Population includes post-traumatic and post-surgical pain, which is not included in FDA approved device indications. 2. Types of pain medication not reported; Broad descriptions of pain sites. 4. Population is not representative of US diversity.			6. Clinically significant difference not supported.	1. Not sufficient duration for durability.

US: United States.

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 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Deer et al (2016)			1. Not registered on clinicaltrials.gov.	1. High loss to follow-up.		

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 intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Hatheway et al (2024) reported on the COMFORT study, a randomized controlled trial investigating the use of an FDA cleared micro-implantable pulse generator.[12] Eligible subjects were randomized to either the active arm, which received peripheral nerve stimulation and conventional medical management, or the control arm, which received conventional medical management alone and were allowed to cross over to the active arm, after 3 months. Pain and patient-reported outcomes were captured. Therapy responders were subjects who achieved at least a 50% reduction in pain scores compared with baseline. At 12 months, the responder rate was 87% with a 69% average reduction in pain compared with baseline (7.5±1.2 to 2.3±1.7; $p<0.001$). Statistical significance was achieved for all patient-reported outcomes. There was an excellent safety profile with no serious adverse device effects or reports of pocket pain. A majority of subjects used unique programming options and found this device easy to use and comfortable to wear. According to the authors, some limitations of this study include the fact that this is not a double-blind study which can increase the risk of expectation bias. Also, the study did not use a questionnaire to assess neuropathic pain but instead relied on the best clinical practice. Furthermore, not all conventional medical management options were available to subjects and were dependent on factors such as physician prescribing practices, patient preference, availability and access to treatment, and insurance coverage of prescribed.

Nonrandomized Studies
Nonrandomized studies have been published[13-15], but do not provide additional information on safety, efficacy, or subgroups beyond what is available in the RCT and will not be reviewed in detail here.

Peripheral Subcutaneous Field Stimulation

Clinical Context and Therapy Purpose
The purpose of PSFS in individuals who have chronic neuropathic 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 neuropathic pain.

Interventions
The therapy being considered is PSfS. Peripheral subcutaneous field stimulation is a modification of peripheral nerve stimulation. In peripheral subcutaneous field stimulation, leads are placed subcutaneously within the area of maximal pain. The objective of peripheral

subcutaneous field stimulation is to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, which then converge back on the spinal cord.

Comparators
The following therapies/tools/rules/practices are currently being used to make decisions about PSFS.

Comparators of interest are medication, exercise or physical therapy, and cognitive-behavioral therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

As a chronic condition, a follow-up of at least 6 weeks to 12 months would be desirable to assess outcomes in chronic neuropathic pain.

Review of Evidence

Randomized Controlled Trials
One crossover RCT compared levels of peripheral subcutaneous field stimulation. McRoberts et al (2013) reported on a randomized, crossover trial of different types of peripheral subcutaneous field stimulation in 44 patients with chronic back pain. In the first phase of the trial, patients rotated through 4 levels of peripheral subcutaneous field stimulation: minimal, subthreshold, low frequency, and standard stimulation.[1] Of 30 patients who completed the first phase, 24 reported that pain was significantly reduced by at least 50% in all of the stimulation groups and were considered responders. In phase 2, a permanent peripheral subcutaneous field stimulation system was placed in 23 responders. During the 52 weeks over which these patients were followed, reported mean visual analog scale scores, present pain index, and total scores on the Short-Form McGill Pain Questionnaire were significantly improved from baseline at all follow-up visits ($p<.001$). Because this trial did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study.

One multi-center RCT compared peripheral subcutaneous field stimulation plus medical management to medical management alone for chronic back pain due to failed back surgery.[2] The study had an open-label design and randomized 116 participants 1:1 to either peripheral subcutaneous field stimulation plus medical management (n=56) or a medical management control group (n=60). Discontinuation was high prior to the 9-month follow-up, with 18 (32%) in the field stimulation and 24 (40%) in the control group; follow-up at the 36-month visit was only available for a single participant in the peripheral subcutaneous field stimulation arm and 3 participants in the control group. This poor rate of long-term follow-up was primarily due to selective early termination of the trial due to recruitment difficulties. The primary endpoint was the response rate which the authors defined as a ≥50% reduction in back pain intensity on the Visual Analogue Scale (VAS). At 9 months, the response rate was significantly higher for combined subcutaneous field stimulation plus medical management (33.9%; 95% CI, 21.5% to 46.3%) compared to medical management alone (1.7%; 95% CI 0% to 4.9%; $p<.0001$) as an intention to treat (ITT) analysis with similar findings on per-treatment and modified ITT

analyses. The mean absolute change from baseline VAS pain score to nine months follow-up was -33.3 mm in the field stimulation group (Standard deviation [SD], 24.5) compared to -2.7 mm (SD,16.0; p<.0001) in the control group. Significant treatment effects were also seen for secondary outcomes on the Oswestry Disability Index, EuroQol quality of life five dimensions (EQ-5DL-5L), and patient global impression of change, which favored combined treatment with peripheral subcutaneous field stimulation plus medical management (p<.001). Forty-nine subjects experienced 1 or more adverse events (29 [52.7%] in the field stimulation arm vs. 20 [33.3%] in the control arm), with the most common etiology classified as an 'other' (defined as non-biological, hardware, therapy, human factors, or medication events). Device-related events amongst implanted patients included 4 (5.0%) device or implant-related infections, 3 (3.8%) lead fractures, and 2 (2.5%) lead dislocation/migrations. Despite early positive findings through 9 months, the trial was limited by a lack of blinding, high loss to follow-up, an absence of longer-term follow-up due to early termination, potential bias in the selection of the comparison group as participants had 6 or more months of prior medication management without a response as an enrollment criterion, and an omission of power calculations.

Nonrandomized Comparative Study

In another comparative study, Mironer et al (2011) used a 2-part evaluation of combined use of spinal cord stimulation and peripheral subcutaneous field stimulation in patients with low back pain.[3] In the first part of the study, 20 patients with failed back surgery syndrome or spinal stenosis underwent a trial with both spinal cord stimulation and peripheral subcutaneous field stimulation and selected the type of stimulation they found most efficacious (program 1: spinal cord stimulation alone; program 2: peripheral subcutaneous field stimulation alone; program 3: combined spinal cord stimulation plus peripheral subcutaneous field stimulation). Patients were blinded to the differences among the programs (randomized order of presentation) and were encouraged to try each program for at least 8 hours; 79% of patients preferred the combined use of spinal cord stimulation plus peripheral subcutaneous field stimulation. In the second part of the study, 20 patients were implanted with spinal cord stimulation and peripheral subcutaneous field stimulation electrodes and selected which program they preferred (spinal cord stimulation and peripheral subcutaneous field stimulation used simultaneously, spinal cord stimulation as anode and peripheral subcutaneous field stimulation as cathode, spinal cord stimulation as cathode and peripheral subcutaneous field stimulation as anode). The programs were presented in a random order, and patients were blinded to the differences among the programs offered. Communication between spinal cord stimulation and peripheral subcutaneous field stimulation was reported to provide wider coverage of axial pain, with an overall success rate (>50% pain relief) of 90%. The most effective program was spinal cord stimulation as cathode and peripheral subcutaneous field stimulation as anode.

Case Series

In addition to the controlled studies, a number of case series have been published, several of which included 50 or more patients. Kloimstein et al (2014) reported on a prospective multicenter study of 118 patients treated with peripheral subcutaneous field stimulation for chronic low back pain.[4] Before patients were implanted with the permanent peripheral subcutaneous field stimulation system, trial stimulation was given for at least 7 days. The permanent stimulation system was implanted in 105 patients. Significant improvements occurred at the 1-, 3-, and 6-month post implantation follow-ups in average visual analog score pain, Oswestry Disability Questionnaire, Beck Depression Inventory, and 12-Item Short-Form

Health Survey scores. Significant reductions in use of opioids, nonsteroidal anti-inflammatory, and anticonvulsant medications were also reported.

Sator-Katzenschlager et al (2010) reported on a retrospective multicenter study of peripheral subcutaneous field stimulation.[5] A total of 111 patients with chronic focal noncancer pain were treated, including 29 patients with low back pain, 37 with failed back surgery syndrome, 15 with cervical neck pain, and 12 patients with postherpetic neuralgia. The median duration of chronic pain was 13 years, and the median number of previous surgeries was 2.7. For permanent implantation of the leads, patients had to have achieved at least 50% reduction in pain on a numeric rating scale during the trial period. After permanent implantation, pain intensity decreased in 102 (92%) patients. Mean pain intensity decreased from 8.2 at baseline to 4.0 at follow-up, with a concomitant reduction in consumption for analgesics and antidepressants. Lead dislocation or fracture occurred in 20 (18%) patients.

Verrills et al (2011) reported on a series of 100 patients treated with peripheral subcutaneous field stimulation for chronic neuropathic pain. Indications included chronic pain occurring among varying regions: occipital/craniofacial (n=40), lumbosacral(n=44), thoracic (n=8), groin/pelvis (n=5), or abdominal (n=3).[6] Selection criteria included a clearly defined, discrete focal area of pain with a neuropathic component or combined somatic/neuropathic pain component with characteristics of burning and increased sensitivity, and failure to respond to other conservative treatments, including medications, psychological therapies, physical therapies, surgery, and pain management programs. Outcomes, assessed at a mean of 8.1 months after implantation (range, 1 to 23 months), included a combination of numeric pain scores, self-report questionnaires, and patient medical histories. For the entire cohort, pain decreased from 7.4 at baseline to 4.2 at follow-up. Pain scores improved by 75% or more in 34% of patients and by 50% or more in 69% of patients. Analgesia use decreased in 40% of patients after peripheral subcutaneous field stimulation. Adverse events were reported in 14% of patients and included unpleasant sensations, lead erosions, and lead or battery migration.

Verrills et al (2014) also reported on peripheral subcutaneous field stimulation for chronic headache conditions.[7] After a trial stimulation period, 60 patients underwent permanent implantation of the peripheral subcutaneous field stimulation system and were followed for an average of 12.9 months (range, 3 to 42 months). Ten patients required revision of the implant system. Significant reductions in pain from baseline were reported ($p \leq .001$). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients, and reductions in degree of disability and depression were noted.

SUMMARY OF EVIDENCE

For individuals who have peripheral, neuropathic, chronic pain who receive peripheral nerve stimulation (PNS), the evidence includes 2 randomized controlled trial (RCT). Relevant outcomes are symptoms, medication use, and quality of life. The RCT reported a statistically significant difference between the treatment group and control group at 90 days in mean reduction in average pain from baseline (27.2% vs. 2.3%; $p<.0001$) and reported 38% responders, defined as having at least a 30% decrease in the numerical rating scale (NRS) with no upward titration in pain medications, in the treatment group. The RCT had a sample size of 94 with broad descriptions of pain diagnoses, including diagnoses beyond the labeled

indications, and a lack of sample population diversity that is not generalizable to the US. There were 51% missing follow-up data at 12 months. Hatheway et al (2024) reported on the COMFORT study, a randomized controlled trial investigating the use of an FDA cleared micro-implantable pulse generator. Eligible subjects were randomized to either the active arm, which received peripheral nerve stimulation and conventional medical management, or the control arm, which received conventional medical management alone and were allowed to cross over to the active arm, after 3 months. According to the authors, some limitations of this study include the fact that this is not a double-blind study which can increase the risk of expectation bias. Also, the study did not use a questionnaire to assess neuropathic pain but instead relied on the best clinical practice. Furthermore, not all conventional medical management options were available to subjects and were dependent on factors such as physician prescribing practices, patient preference, availability and access to treatment, and insurance coverage of prescribed. Additional evidence from RCTs with larger sample sizes and longer durations of comparative data are necessary to assess the efficacy and durability of PNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes 2 randomized controlled trials (RCTs), a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT, McRoberts et al (2013), which used a crossover design, did not compare peripheral subcutaneous field stimulation with alternatives. Rather, it compared different methods of peripheral subcutaneous field stimulation. Among trial participants, 24 (80%) of 30 patients had at least a 50%reduction in pain with any type of peripheral subcutaneous field stimulation. However, because the RCT did not include a sham group or comparator with a different active intervention, this trial offers little evidence for efficacy beyond that of a prospective, uncontrolled study. An open-label RCT found that peripheral subcutaneous field stimulation plus medical management had a greater rate of pain reduction compared to medical management alone at 9 months follow-up. Secondary outcomes found benefits in several quality-of-life indices over medical management alone. The trial had a high loss to follow-up and was terminated early as a result of recruitment challenges, which impacted the durability and certainty of these findings. Case series are insufficient to evaluate patient outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Larger, prospective controlled trials comparing peripheral subcutaneous field stimulation with placebo or alternative treatment modalities are needed to determine the efficacy of peripheral subcutaneous field stimulation for chronic pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT04246281	SPRINT® peripheral nerve stimulation for the treatment of back pain	230	Feb 2027
NCT04713098	Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacologic Alternative for the Treatment of Postoperative Pain	250	Dec 2025
NCT04246281[a]	A Randomized, Controlled, Multicenter Trial of Percutaneous Peripheral Nerve Stimulation (PNS) for the Treatment of Back Pain	230	Dec 2027
NCT06331871	Effectiveness of US-PENS for Patients with Post-surgical Shoulder Pain	70	Oct 2025
NCT05870124[a]	Clinical Study of a Micro-Implantable Pulse Generator for The Treatment of Peripheral Neuropathic Pain (COMFORT2)	100	Apr 2025
NCT03913689[a]	A Prospective, Open-label, Long-term, Multi-center, Registry to Assess the Safety and Efficacy of the Bioness StimRouter Neuromodulation System in Subjects with Chronic Pain of Peripheral Nerve Origin	173	Apr 2028
Unpublished			
NCT03783689[a]	The SNAP trial: SPRINT peripheral nerve stimulation for the treatment of neuropathic post-amputation pain in a randomized, double-blinded, placebo-controlled multicenter trial	126	Oct 2022
NCT02893267	Multimodal treatment for hemiplegic shoulder pain	132	Dec 2022
NCT04341948[a]	Treatment of Post-Operative Pain Following Orthopedic Surgery With SPRINT® Peripheral Nerve Stimulation (PNS) System in a Randomized, Double-Blinded, Placebo-Controlled Trial	150	Apr 2024
NCT03752619	Peripheral nerve stimulation (PNS) for subacromial impingement syndrome (SIS)	116	Jan 2023
NCT04670042	Using PNS to treat chronic post-surgical pain after knee surgery	15	Nov 2023 (withdrawn)

NCT: national clinical trial; ISRCTN: international standard RCT number

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) issued guidance (2013) on peripheral subcutaneous field stimulation for chronic low back pain, which stated:[17]

> "Current evidence on the efficacy of peripheral nerve-field stimulation for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device."

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience published consensus clinical guidelines for the use of implantable peripheral nerve stimulation in the treatment of chronic pain based on a review of the literature through March 2021.[16] Recommendations for best practices are listed below in Table 8.

Table 8. American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	DOR
Head and Neck		
Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatment has failed. The average effect size for relief of migraine symptoms is modest to moderate.	I	B
There is presently insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain	II-3	C
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
Low Back and Trunk		
Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone.	I	B
There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain.	II-2	B
There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia.	III	C
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
CRPS		
As a less-invasive modality compared to SCS therapy, PNS may be offered to patients with CRPS Type I/II or peripheral causalgia and may be associated with modest improvement in pain intensity and functional outcomes. However, high-quality evidence is limited and other neuromodulation interventions such as dorsal root ganglion SCS are recommended.	III	C
Other Considerations		
PNS carries a low-to-intermediate risk for bleeding complications and depends on the proximity of the targeted nerve to critical vessels and invasiveness of PNS implantation.	III	I

CRPS: complex regional pain syndrome; DOR: degree of recommendation; LOE: level of evidence; PNS: peripheral nerve stimulation; SCS: spinal cord stimulator.

Government Regulations

National:

NCD (160.7) effective 08/07/1995.[18] "Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.

"Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.
"Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator."

Local:

There is no local coverage determination (LCD) on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Interferential Stimulation
- Neuromuscular Electrical Stimulation
- Occipital Nerve Stimulation
- Percutaneous Electrical Nerve Stimulation (PENS), Percutaneous Neuromodulation Therapy (PNT), and Restorative Neurostimulation Therapy
- Spinal Cord Stimulation

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/14	12/10/13	1/6/14	Joint policy established
9/1/15	6/19/15	7/16/15	Routine maintenance
9/1/16	6/21/16	6/21/16	Routine policy maintenance. No change in policy status.
5/1/17	2/21/17	2/21/17	Deleted codes 0282T-0285T, added code 64999.
5/1/18	2/20/18	2/20/18	Routine policy maintenance. No change in policy status.
5/1/19	2/19/19		Routine policy maintenance. Policy statement unchanged.
5/1/20	2/18/20		Routine policy maintenance. MPS unchanged.
5/1/21	2/16/21		Routine policy maintenance.
5/1/22	2/15/22		Expanded policy to include non-coverage of PNS therapy, rationale updated, description section updated, references 1-3 and 6 added. No change in policy status.
5/1/23	2/21/23		Added code 64555 as E/I. (ds)
5/1/24	2/20/24		Updated rationale, added references 12 & 13. Added codes 64596-64598 as E/I, effective 1/1/24. No change in policy status. Vendor managed: N/A (ds)
5/1/25	2/18/25		Routine policy maintenance, no change in status. Vendor managed: N/A (ds)
7/1/25	4/22/25		Policy rewritten, PSFS and PNS separated, no change in policy status. Added reference #12. Title change, PNS placed before PSFS, added “implantable” and “treatment for chronic pain.” Vendor managed: N/A (ds)

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: IMPLANTABLE PERIPHERAL NERVE STIMULATION AND PERIPHERAL SUBCUTANEOUS FIELD STIMULATION DEVICES FOR THE TREATMENT OF CHRONIC PAIN

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A