Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Title: Peripheral Subcutaneous Field Stimulation and Peripheral Nerve Stimulation

Description/Background

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.

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. There is insufficient evidence to support the safety and effectiveness of PNS for the treatment of any indication including chronic pain.

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.

Regulatory Status

StimRouter Neuromodulation System (Bioness Inc., Valencia, CA) received 510(k) approval in 2015 as a class II device. The device 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 (e.g., medication). It is not intended to treat pain in the craniofacial region.

StimQ Peripheral Nerve Stimulator (PNS) (Stimwave Technologies Incorporated, Ft. Lauderdale FL) system received 510(k) approval in 2017 as a class II device. The approval included indications for use: the device 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 StimQ PNS System is not intended to treat pain in the craniofacial region. The StimQ Trial Lead Kit is only used in conjunction with the StimQ Stimulator Receiver Kit. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

In July 2018, the SPRINT® Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (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.

In October 2022, the indications for use were clarified to note that the system is not intended to be placed in the region innervated by the cranial and facial nerves.

Medical Policy Statement

Peripheral nerve stimulation (PNS) therapy and peripheral subcutaneous field stimulation (PSFS) is experimental/investigational. They have not been scientifically demonstrated to improve patient clinical 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.

Clinical Context and Therapy Purpose
The purpose of PNS therapy and 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 PNS and PSFS.

PNS/PSFS is performed in inpatient and outpatient settings. individuals with chronic neuropathic pain are managed by general practitioners and, in cases that are difficult to treat, by pain specialists.

Comparators
The following therapies/tools/rules/practices are currently being used to make decisions about PNS/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
In 2012, Silberstein et. Al published a randomized, controlled, double-blinded multicenter study on the safety and efficacy of peripheral nerve stimulation (PNS) of the occipital nerves for the management of chronic migraine in 157 patients.[1] The patients were randomized to active treatment (n=105) or sham treatment (n=52).The primary endpoint was a difference in the percentage of responders (defined as patients that achieved a ≥50% reduction in mean daily visual analog scale scores) in each group at 12 weeks. There was not a significant difference in the percentage of responders in the Active compared with the Control group (95% lower confidence bound (LCB) of -0.06; p = 0.55). However, there was a significant difference in the percentage of patients that achieved a 30% reduction (p = 0.01). Importantly, compared with sham-treated patients, there were also significant differences in reduction of number of headache days (Active Group = 6.1, baseline = 22.4; Control Group = 3.0, baseline = 20.1; p =

0.008), migraine-related disability (p = 0.001) and direct reports of pain relief(p = 0.001). The most common adverse event was persistent implant site pain. The authors concluded, although this study failed to meet its primary endpoint, this is the first large scale study of (PNS) of the occipital nerves in chronic migraine patients that showed significant reductions in pain, headache days, and migraine-related disability. Additional controlled studies are warranted in this highly disabled patient population with a large unmet medical need.

In 2016, Deer et. Al. published a prospective, multicenter, randomized, double-blinded, partial crossover study to assess the safety and efficacy of the StimRouter neuromodulation system in the treatment of 94 patients with chronic pain of peripheral nerve origin.[2] After IRB approval, patients were enrolled, implanted, and then followed for three months to assess efficacy and one year for safety based on Food and Drug Administration guidance. The patients were randomized to the treatment StimRouter group (45) or the control group (n=49). The primary efficacy endpoint, three months after randomization to treatment, demonstrated that patients receiving active stimulation achieved a statistically significantly higher response rate of 38% vs. the 10% rate found in the Control group (p = 0.0048). Improvement in pain was statistically significant between the randomized groups, with the treatment group achieving a mean pain reduction of 27.2% from Baseline to Month 3 compared to a 2.3%reduction in the Control group (p < 0.0001). During the partial crossover period, patients again demonstrated statistically significant improvement in pain relief with active stimulation compared to baseline. Further, the treatment group had significantly better improvement than the control group in secondary measures including but not limited to quality of life and satisfaction. Safety, assessed throughout the trial and with follow-up to one year, demonstrated no serious adverse events related to the device. All device-related adverse events were minor and self-limiting. However, the results need confirmation in additional randomized controlled trials (RCTs) with longer follow-up to draw conclusions. Studies should also compare StimRouter with other peripheral nerve stimulation systems such as spinal cord stimulation and alternative treatments.

Gilmore et al (2019) conducted a double-blinded, randomized, placebo-controlled study with twenty-eight lower extremity amputees with postamputation.[3] The subjects underwent ultrasound-guided implantation of percutaneous PNS leads and were randomized to receive PNS (with SPRINT, SPR Therapeutics), or placebo for four weeks. The placebo group then crossed over and all subjects received PNS for four additional weeks. The primary efficacy endpoint evaluated the proportion of subjects reporting ≥50% pain reduction during one to four weeks. A greater proportion of subjects receiving PNS (n=7/12, 58%, p=0.037) demonstrated ≥50% reductions in average postamputation pain during weeks one through four compared with subjects receiving placebo (n=2/14, 14%). Two subjects were excluded from efficacy analysis due to eligibility changes. Greater proportions of PNS subjects also reported ≥50% reductions in pain (n=8/12, 67%, p=0.014) and pain interference (n=8/10, 80%, p=0.003) after 8 weeks of therapy compared with subjects receiving placebo (pain: n=2/14, 14%; pain interference: n=2/13, 15%). Limitations of the study included small number of subjects.

One crossover RCT compared levels of PSFS. McRoberts et al (2013) reported on a randomized, crossover trial of different types of PFSF in 44 patients with chronic back pain. In the first phase of the trial, patients rotated through 4 levels of PFSF: minimal, subthreshold, low frequency, and standard stimulation.[4] 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 PFSF 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<0.001). Because this trial did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study.

Johnson et al (2021) conducted a 2-part study comprised of a double-blind, sham controlled RCT followed by an open-label mechanistic study to determine the impact of external non-invasive peripheral electrical nerve stimulation (ENPENS) in adults with chronic moderate to severe peripheral nerve injury pain.[5] Patients were randomized to either active ENPENS or sham for 3 months (minimum 10 minutes daily). The primary outcome was change in average pain intensity (on a 0 to 10 Likert scale) after ENPENS or sham. Seventy-six patients were randomized (38 per group), with 65 (31 active, 34 sham) included in the intention-to-treat analysis. After adjusting for baseline scores, pain scores were 0.3 units lower in the active group, but not significantly different from the sham group (p=.30). Nineteen patients continued on to the open-label ENPENS mechanistic study after the RCT. In the open-label phase, primary outcomes of mechanical pain sensitivity (p=.006) and mechanical allodynia (p=.043) significantly improved, indicating reduced sensitivity to pain with low-frequency nerve stimulation. Results from the RCT failed to reach significance and the results from the open-label portion were limited by the small sample size and lack of a comparator group.

Ilfeld et al (2021) published the results of a randomized, sham-controlled, pilot study of peripheral nerve stimulation (PNS) for the treatment of postoperative pain in individuals receiving foot, ankle, knee, or shoulder surgery.[12,] Subjects were randomized to 14 days of electrical PNS stimulation (n=32) or sham stimulation (n=34). The dual primary outcomes were cumulative opioid consumption and mean daily pain scores within the first 7 postoperative days. Both outcomes met superiority thresholds with median opioid consumption of 5 mg versus 48 mg (estimated ratio of geometric means, 0.20; 97.5% CI, 0.07 to 0.57; p<.001) and average pain intensity of 1.1 versus 3.1 (difference in means, -1.8; 97.5% CI, -2.6 to -0.9; p<.001) as assessed by the Brief Pain Inventory-Short Form (BPI-SF) in treatment and sham groups, respectively. Differences in average pain, worst pain, and pain as assessed by the Defense and Veterans Pain Rating Scale were not significantly different between groups following completion of the treatment period on postoperative days 15 and 30.

Albright-Trainer et al (2022) conducted a randomized controlled feasibility trial of PNS for the management of post-amputation pain.[13] Sixteen U.S. veterans undergoing major lower limb amputation at a single center received up to 60 days of PNS with the SPRINT system and standard medical therapy (n=8) or standard medical therapy alone (n=8). Standard medical therapy was defined as routine use of opioid and non-opioid pain medications, injections, physical rehabilitative therapies or complementary and alternative therapies. Responders were defined as participants with a at least a 50% reduction in average residual and phantom limb pain over time as assessed by the Brief Pain Inventory-Short Form (BPI-SF), with greater than 50% improvement considered substantial. At 12 weeks of follow-up, the PNS group experienced a 76% and 100% reduction in average phantom and residual limb pain from baseline compared to 58% and 75% in the control group, respectively. Additionally, only 20% of patients in the PNS group were taking opioids at 12 weeks compared to 38% in the control group. No patients in the PNS group required hospital readmission within 30 days compared to

25% requiring readmission in the control group. Follow up analysis through 12 months is ongoing. No serious study-related adverse events were reported. Follow-up at 12 weeks was missing for 3 individuals in the PNS group (termination due to unrelated medical events [2] and withdrawal of consent [1]) and 1 individual in the control group (withdrawal of consent). The authors concluded that larger studies are warranted to reproduce the encouraging results of their feasibility study and to elucidate optimal timing of PNS therapy, evaluate surgical indications, and optimize patient selection.

Nonrandomized Comparative Study

In comparative study, Mironer et al (2011) used a 2-part evaluation of combined use of spinal cord stimulation and PSFS in patients with low back pain.[6] 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 PSFS 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 PFSF. In the second part of the study, 20 patients were implanted with spinal cord stimulation and PSFS electrodes and selected which program they preferred (spinal cord stimulation and PSFS used simultaneously, spinal cord stimulation as anode and peripheral subcutaneous field stimulation as cathode, spinal cord stimulation as cathode and PSFS 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 PSFS 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 PSFS as anode.

Case Series

Warner et al (2020) reports on a retrospective case series of adults undergoing PNS implantation from 2004 to 2017 at an academic medical center.[7] The primary outcomes were changes in numeric rating scale (NRS) pain scores, opioid utilization in oral morphine milligram equivalent (MME), and self-reported patient functioning at 6 months postoperatively. Infectious and device-related complications were also assessed. A total of 72 patients underwent PNS implantation, including 59 patients that received a preceding PNS trial (59/78; 76% progression rate) and 13 that did not receive a PNS trial. The most common indication for stimulation was occipital neuralgia (47%) followed by lower-extremity neuropathies (17%). PNS implantation was associated with 6-month reductions in pain scores (7 [6, 8] baseline vs. 4 [2, 5] 6 months; $P < 0.001$) and opioid utilization (e.g., median 60 [31, 104] vs. 18 [0, 52] MME among those with baseline opioid use; $P < 0.001$). Median functional improvement was 73% (50%, 88%). Seven patients (10%) suffered a postoperative surgical site infection at a median of 50 (30, 124) days, of which five devices were removed. Although PNS was associated with reduced pain scores and lower opioid utilization, prospective multicenter evaluation is warranted to evaluate long-term outcomes.

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.[8] Before patients were implanted with the permanent PSFS 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 PSFS.[9] 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 PSFS 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).[10] 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, 1-23 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 PSFS for chronic headache conditions.[11] After a trial stimulation period, 60 patients underwent permanent implantation of the PSFS system and were followed for an average of 12.9 months (range, 3-42 months). Ten patients required revision of the implant system. Significant reductions in pain from baseline were reported ($p \leq 0.001$). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients, and reductions in degree of disability and depression were noted.

A retrospective case series by Warner et al (2020) reported on adults undergoing peripheral nerve stimulation implantation at an academic medical center.[12,] The primary outcomes were changes in numeric rating scale pain scores, opioid use in oral morphine milligram equivalent (MME), and self-reported patient functioning at 6 months post-implantation. A total of 72 patients underwent peripheral nerve stimulation implantation. The most common indication for stimulation was occipital neuralgia (47.3%) followed by lower-extremity neuropathies (16.5%). Peripheral nerve stimulation implantation was associated with a 6-month reduction in pain scores (median baseline score 7 vs median score 4 at 6 months; $p<.001$) and opioid utilization

(median 60 MME at baseline vs median 18 MME among those with baseline opioid use [n=25]; p<.001). All patients reported improvement in daily functioning, with median improvement of 73% post-implantation.

SUMMARY OF EVIDENCE

For individuals who have chronic neuropathic pain who receive peripheral nerve stimulation (PNS) therapy, the evidence is limited to a small number of randomized controlled trials and case series that suggests implantable PNS is safe and works as intended to treat chronic pain or peripheral nerve origin. However, results need confirmation in additional randomized controlled trials with longer follow-up to draw conclusions on safety and efficacy. Further studies should also compare implantable PNS with other neurostimulation therapy such as spinal cord stimulation and alternative treatments. The evidence is insufficient to determine the effects of this technology on net health outcomes.

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation (PSFS), the evidence includes four RCTs, a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, 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. Another RCT by Johnson et al (2021) compared sham to external non-invasive peripheral electrical nerve stimulation, but found no significant differences in pain scores between groups after intervention. A third small, pilot RCT by Ilfeld et al (2021) found significantly reduced opioid consumption and mean daily pain scores within the first 7 postoperative days in subjects receiving foot, ankle, knee, or shoulder surgery. However, differences in average pain, worst pain, and Defense and Veterans Pain Rating Scale scores were not significantly different between treatment and sham groups following completion of the treatment period on postoperative days 15 and 30. A fourth small, pilot feasibility RCT by Albright-Trainer et al (2022) compared peripheral nerve stimulation with standard medical care to standard medical care alone in veterans undergoing lower extremity amputation. Greater reductions in average phantom limb pain, residual limb pain, and daily opioid consumption were reported through 3 months with the addition of peripheral nerve stimulation. 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 1.

Table 1. 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:[11]

> "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.[11,] Recommendations for best practices are listed below in Table 2.

Table 2. 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 have 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. "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
- 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 January 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)

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PERIPHERAL SUBCUTANEOUS FIELD STIMULATION AND PERIPHERAL NERVE STIMULATION

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