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Peripheral Nerve Stimulation (PNS) And Peripheral Nerve Field Stimulation (PNFS)

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Related Policies (if applicable)
None

Disclaimer

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Coverage

Peripheral nerve stimulation and peripheral nerve field stimulation (also called peripheral subcutaneous field stimulation) are considered experimental, investigational and/or unproven.

Policy Guidelines

None.

Description

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, 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 (SCS), are established methods of chronic pain treatment. Peripheral nerve stimulation (PNS) and peripheral nerve field stimulation (PNFS; also known as peripheral subcutaneous field stimulation) are addressed within this medical policy.

Peripheral Nerve Stimulator (PNS)

PNS or percutaneous peripheral nerve stimulation involves the implantation of wire-like electrodes near a peripheral nerve that is located beyond the brain or spinal cord that is identified as transmitting pain to a specific area of the body. The process of implantation usually involves two phases – a temporary test, followed by implantation of the programmable generator and/or battery pack if testing is successful. (1)

Peripheral Nerve Field Stimulation (PNFS)

Peripheral nerve field stimulation (PNFS; also called peripheral subcutaneous field stimulation (PSFS); or target field stimulation) is a form of neuromodulation intended to treat chronic neuropathic pain.

PNFS is a modification of peripheral nerve stimulation. In PNFS, leads are placed subcutaneously within the area of maximal pain. The objective of PNFS 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. Combination SCS plus PNFS is also being evaluated.

Similar to SCS or PNS, 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 PNFS. Criteria for a trial of PNFS 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 PNFS is unknown. Theories include an increase in endogenous endorphins and other opiate-like substances; modulation of smaller A delta and C nerve 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 PNFS include lead migration or breakage and infection of the lead or neurostimulator.

Regulatory Status

Peripheral Nerve Stimulator (PNS)

In 2015, StimRouter Neuromodulation System (Bioness Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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. FDA product code GZF. (2)

In 2016, StimQ Peripheral Nerve Stimulator (PNS) (Stimwave Technologies Incorporated) was cleared for marketing by the U.S. FDA through the 510(k) process as a class II device. The FDA 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. FDA product code GZF. (3)

In July 2018, the SPRINT® Peripheral Nerve Stimulation System (SPR Therapeutics, Inc.) was cleared for marketing by the U.S. FDA through the 510(k) process as a class II device (K181422). The FDA determined that this device was substantially equivalent to existing devices for use in pain management. The FDA approved the Sprint PNS system for use up to 60 days for use in the back and/or extremities for symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain; symptomatic relief of post-traumatic pain; and symptomatic relief of post-operative pain. The sprint PNS system is not intended to treat pain in the craniofacial region. FDA product code: NHI. (4)

In 2019, the Nalu Neurostimulation System for PNS (K183579; Nalu Medical Inc.) was cleared for marketing by the U.S. FDA through the 510(k) process as a class II device. (5) In March 2021, the FDA approved Nalu for both spinal cord stimulation and PNS (K203547). The PNS indication is approved for adults with severe intractable chronic pain of peripheral nerve origin. The system is not intended to treat pain in the craniofacial region. Per the FDA label, use of the device involves up to 30 days of trial stimulation to determine efficiency prior to permanent implantation. (6) FDA product code ZGB/ZGF.

NOTE: Peripheral subcutaneous field stimulation is an off-label use of peripheral nerve stimulation systems that have been approved by the FDA for the treatment of chronic pain by targeting one or more peripheral nerves associated with pain.

Refer to <https://fda.gov> for additional U.S. FDA approved devices with their specific indication for use.

Rationale

Medical policies assess whether the clinical evidence is sufficient to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, 2 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Peripheral Nerve Stimulator (PNS)

Deer et al. (2016) conducted a prospective, multicenter, randomized, double-blind, partial crossover study to evaluate the safety and efficacy of the StimRouter System for use in the treatment of severe, intractable pain of peripheral nerve origin associated with posttraumatic or postsurgical neuralgia, exclusive of the craniofacial region. (7) Ninety-four patients were randomized to treatment group (n=45) or control group (n=49). Primary outcomes included pain relief and safety, measured by average pain at rest using a numerical rating scale followed for three months, and safety, determined by assessment of adverse events during the one-year study period. Treatment group received electrical stimulation (StimRouter system) and stable dosing of pain medications, while the control group received no therapeutic stimulation and a stable dose of pain medications. At 3 months, patients receiving active stimulation achieved a higher response rate of 38% vs. 10% rate in the control group ($p = 0.0048$). The treatment group achieved a mean pain reduction of 27.2% from baseline to month 3 compared to a 2.3% reduction in the control group ($p<0.0001$). Safety was assessed throughout the trial and with follow-up to 1 year demonstrated no serious adverse events related to the device. For safety follow-up, 15 did not participate in the 6 and 12-month follow-up and 33 patients at 12-month follow-up, representing an attrition of 51%.

Gilmore et al. (2019) conducted a double-blinded, randomized, placebo-controlled study with twenty-eight lower extremity amputees (postamputation). (8) Subjects underwent ultrasound-guided implantation of percutaneous PNS leads and were randomized to receive PNS (with SPRINT, SPR Therapeutics), or placebo for 4 weeks. The placebo group then crossed over and all subjects received PNS for 4 additional weeks. The primary efficacy endpoint evaluated the proportion of subjects reporting ≥50% pain reduction during 1 to 4 weeks. A greater proportion of subjects receiving PNS (n=7/12, 58%, p=0.037) demonstrated ≥50% reductions in average postamputation pain during weeks 1 through 4 compared with subjects receiving placebo (n=2/14, 14%). 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.

Gilmore et al. (2019) (9) reported on 12-month outcomes in the prior cohort which noted that more participants in group 1 reported ≥50% reductions in average weekly pain at 12 months (67%, 6/9) compared with group 2 at the end of the placebo period (0%, 0/14, p=0.001). Additionally, 56% (5/9) of participants in group 1reported ≥50% reductions in pain interference at 12 months, compared with 2/13 (15%, p=0.074) in group two at crossover. Limitations of the study included the small number of subjects at 12 months and the loss of participants to follow-up.

Deer et al. (2020) conducted a systematic review of 14 RCTs (n=20-157) which evaluated PNS for the treatment of pain. (10) Indications for treatment included headache (6 studies, n=389), shoulder pain (2 studies, n=50), leg and/or back pain (4 studies, n=306), and pelvic pain (3 studies, n=146). RCTs evaluating PNS or PNFS in patients with intractable pain were included. Excluded were retrospective studies and RCTs with less than 2 months of follow-up. The primary outcome measure was improvement in pain. Intervention and duration of treatment varied widely, as did comparators (e.g., “usual care”, physical therapy, sham treatment). Follow ups ranged from three months to one year (median 7 months). Due to the heterogeneity of patient populations, diagnoses, interventions, comparators, outcome measures, and study designs, a quantitative meta-analysis was not completed. The authors concluded that several studies indicated occipital nerve stimulation can be beneficial for chronic migraine, medication overuse headache, and intractable chronic migraine; there was moderate evidence that implanted sphenopalatine ganglion stimulation is effective for cluster headaches; there was strong evidence that PNFS is beneficial for patients with continued low back pain following surgery, medications, and/or interventional pain procedures; there was moderate evidence that implanted PNS can provide at least modest improvement in mononeuropathic pain and hemiplegic shoulder pain; and fair evidence that peripheral tibial nerve stimulation (PTNS) may be helpful for overall pain, dyspareunia, and chronic pelvic pain. Many studies lacked a true control group and/or blinding. Other limitations of included studies were the relatively small sample sizes and short duration of follow-up.

Some controlled studies have been completed; however, evidence is primarily in the form of case reports, retrospective reviews, and case series with small patient populations, short

duration of follow-up, and/or lack of a sham or untreated control groups. (7-8, 11-20, 35) Systematic reviews evaluating PNS for the treatment of various pain conditions have been published in the literature. Most include prospective and retrospective studies of varying size, with wide variations in patient populations, interventions, and study design. Authors consistently note a lack of high-quality RCTs, and heterogeneity among the studies which precludes meta-analysis (8, 19, 20). There remains poor understanding of the underlying mechanisms of PNS, appropriate patient selection, or long-term outcomes of therapy. Currently studies are primarily in the form of case reports, retrospective reviews and case series, with small patient populations along with one small RCT therefore, the evidence is insufficient to support the long-term safety and effectiveness of PNS for any indication.

ECRI

In 2020, ECRI (23) evaluated clinical evidence related to the use of the StimRouter device for treating nerve pain and deemed the evidence is "inconclusive" due to too few data. ECRI states there is limited evidence from one small, multicenter, RCT that suggests that StimRouter is safe, and it relieved chronic neuropathic pain and improved QOL in slightly more than one-third of patients at 3 months follow-up compared with sham treatment. The RCT is limited by a small sample size and provided only short-term follow-up data for a device intended for long-term use. No evidence is available comparing StimRouter to other nerve stimulation systems or other pain management techniques. Findings may not generalize across patients with different pain etiologies. However, additional RCTs are needed to validate these results and to address other evidence gaps (comparisons to other pain management technologies).

In 2023, ECRI (24) evaluated the clinical evidence specific to Sprint PNS for peripheral nerve pain and deemed the evidence is "inconclusive" due to "too few comparative data". PNS with Sprint is intended as an alternative to other treatments for individuals with different types of pain or with pain in different anatomic regions (e.g., nerve blocks, neurostimulation with permanent implants, transcutaneous electric stimulation, epidural anesthesia). Available studies report Sprint achieves clinical pain relief and improved physical function in individuals with varied pain etiologies and that serious adverse events are rare. However, available comparative studies provide insufficient evidence to determine how Sprint compares with other pain management interventions for improving patient outcomes because they assess too few patients per comparison or per patient population. Studies assessing Sprint for treating chronic pain report on too few patients with follow-up of 1 year or more after Sprint removal to enable firm conclusions about outcome sustainability. Two RCTs suggest Sprint is more effective than physical therapy and a cuff-type sling for treating chronic hemiplegic shoulder pain. Although PNS has established safety and effectiveness, large multicenter trials with long-term data (i.e., one year and beyond) are needed to validate Sprint's sustained benefits after removal and determine comparative safety and effectiveness.

In 2023, ECRI (25) evaluated the clinical evidence specific to implantable PNS devices for treating chronic pain. Findings from the systematic reviews and 4 additional low-quality case series suggest PNS is safe, may reduce opioid consumption, and may improve QOL in select patient populations with chronic pain although no studies compared PNS with other chronic

pain management methods. ECRI stated that studies in the systematic reviews had high heterogeneity, which prevented synthesizing data in the meta-analyses. Although all RCTs included in 2 systematic reviews reported pain reduction, these studies varied in comparison groups, pain etiologies, and follow-up duration, and all reported relatively short follow-up (12 months or less) for a treatment that is intended to be used long-term. Additional available studies, including some reviewed in the systematic reviews, are at considerable risk of bias due to small sample size, retrospective design, single center focus, or lack of randomization, blinding, or controls. Large RCTs are needed that compare PNS with other chronic pain management techniques and report on long-term outcomes.

Peripheral Nerve Field Stimulation (PNFS)

Chronic Neuropathic Pain

Clinical Context and Therapy Purpose

The purpose of peripheral nerve field stimulation (PNFS; also called peripheral subcutaneous field stimulation (PSFS); or target field stimulation) 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 policy.

Populations

The relevant population of interest is individuals with chronic neuropathic pain.

Interventions

The therapy being considered is PNFS. PNFS is a modification of peripheral nerve stimulation. In PNFS, leads are placed subcutaneously within the area of maximal pain. The objective of PNFS 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 are currently being used to make decisions about PNFS: pharmacotherapy, exercise or physical therapy, and cognitive-behavioral therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, QOL, 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- 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.

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. (26) Of 30 patients who completed the first phase, 24 reported that pain was significantly reduced by at least 50% in all 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. (27) 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. used a 2-part evaluation of combined use of spinal cord stimulation (SCS) and PNFS in patients with low back pain (28) In the first part of the study, 20 patients with failed back surgery syndrome or spinal stenosis underwent a trial with both SCS and PNFS and selected the type of stimulation they found most efficacious (program 1: SCS alone; program 2: PNFS alone; program 3: combined SCS plus PNFS). 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 SCS plus PNFS. In the second part of the study, 20 patients were implanted with SCS and PNFS electrodes and selected which program they preferred (SCS and PSFS used simultaneously, SCS as anode and PNFS as cathode, SCS as cathode and PNFS as anode). The programs were presented in a random order, and patients were blinded to the differences among the programs offered. Communication between SCS and PNFS was reported to provide wider coverage of axial pain, with an overall success rate (>50% pain relief) of 90%. The most effective program was SCS as cathode and PNFS 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 PNFS for chronic low back pain. (29) Before patients were implanted with the permanent PNFS 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 (VAS) pain, Oswestry Disability Questionnaire, Beck Depression Inventory, and 12-Item Short-Form Health Survey scores. Significant reductions in use of opioid, nonsteroidal anti-inflammatory, and anticonvulsant medications were also reported.

Sator-Katzenschlager et al. (2010) reported on a retrospective multicenter study of PNFS. (30) 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 PNFS for chronic neuropathic pain. (31) 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). 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 PNFS. 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 PNFS for chronic headache conditions. (32) After a trial stimulation period, 60 patients underwent permanent implantation of the PNFS 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.

Summary of Evidence

For individuals who have chronic pain who receive peripheral nerve stimulation (PNS) there are few randomized controlled trials (RCTs) available in the published literature and all have small sample sizes, and some with a high risk for bias. Some prospective controlled studies have been completed; however, evidence is primarily in the form of case reports, retrospective reviews, and case series with small patient populations, short duration of follow-up, and lack of a sham or untreated control group. Therefore, the current evidence is insufficient to determine that the technology results in an improvement in the net health outcome long term.

For individuals who have chronic neuropathic pain who receive peripheral nerve field stimulation (PNFS), the evidence includes 2 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 PNFS with alternatives. Rather, it compared different methods of PSFS. Among trial participants, 24 (80%) of 30 patients had at least a 50% reduction in pain with any type of PSFS. 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 PNFS 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 PNFS with placebo or alternative treatment modalities are needed to determine the efficacy of PNFS for chronic pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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. (33) Recommendations for best practices are listed below in Table 1.

Table 1. American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines (8)

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.

National Institute for Health and Care Excellence

In 2013, the National Institute for Health and Care Excellence (NICE) issued guidance on PNFS for chronic low back pain, which stated (34 "Current evidence on the efficacy of peripheral nerve-field stimulation (PNFS) 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."

Ongoing and Unpublished Clinical Trials

No ongoing or unpublished clinical trials were identified.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	64555, 64575, 64580, 64585, 64590, 64595, 64596, 64597, 64598, 64999, 95970, 95971, 95972
HCPCS Codes	A4438, A4595, C1767, C1778, C1787, C1816, C1820, C1822, C1883, C1897, C9807, L8678, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change

02/01/2025	Document updated with literature review. Coverage unchanged. Added references 5, 6, 10-16; 21, 22, 25, 27, 33, 35; others updated/some removed.
02/15/2024	Document updated. Content on Reactiv8 moved to policy MED205.032. Multiple references removed.
09/15/2023	Reviewed. No changes.
10/01/2022	Document updated with literature review. Coverage unchanged. Added references 5, 10-15, 26, 32; others updated.
12/01/2021	Reviewed. No changes.
05/01/2021	Document updated with literature review. The following changes were made in Coverage: 1) Added peripheral nerve stimulation to the experimental, investigational and/or unproven statement. 2) Changed terminology from "peripheral subcutaneous field stimulation" to "peripheral nerve field stimulation". Added references 1-17, 24; others updated. Title changed from "Peripheral Subcutaneous Field Stimulation".
08/01/2019	Document updated with literature review. Coverage unchanged. No new references added.
06/15/2018	Reviewed no changes.
07/15/2017	Document updated with literature review. Coverage unchanged.
02/01/2017	Reviewed no changes.
08/01/2015	Document updated with literature review. Coverage unchanged.
07/01/2014	Reviewed no changes.
10/15/2013	New medical document. Peripheral subcutaneous field stimulation is considered experimental, investigational and unproven. (Coverage is unchanged. This topic was previously addressed on MED205.032, Percutaneous and Implanted Nerve Stimulation and Neuromodulation).