Peripheral Subcutaneous Field Stimulation (PSFS)

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DESCRIPTION

Peripheral subcutaneous field stimulation (PSFS); also called peripheral nerve field stimulation (PNFS) or target field stimulation is a form of neuromodulation that is intended to treat chronic neuropathic pain. Applications of PSFS being evaluated are craniofacial stimulation for headache/migraine, craniofacial pain, or occipital neuralgia. PSFS is also being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and post-herpetic neuralgia.

Chronic Pain

Chronic, non-cancer pain is responsible for a high burden of illness. Common types of chronic pain include lumbar and cervical pain, chronic headaches, and abdominal pain. All 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. These include analgesics (opioid and non-opioid),

antidepressants, anticonvulsants, and muscle relaxants. There also are a variety of non-pharmacologic treatments, including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, chiropractic, and therapeutic massage.

Neuromodulation is another form of non-pharmacologic therapy that is usually targeted toward patients with chronic pain that is 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, which involves placement of an electrical stimulator on the peripheral nerve, is also used for neuropathic pain originating from peripheral nerves.

Peripheral Subcutaneous Field Stimulation

Peripheral subcutaneous field stimulation (PSFS) is a modification of implantable peripheral nerve stimulation. In PSFS, leads are placed subcutaneously (subdermal level) to stimulate the small nerve fibers in that layer of the area of maximal pain. The objective is to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, and change the message at the spinal cord level. Combination spinal cord stimulation plus peripheral subcutaneous field stimulation 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 regarding the indications for PSFS. Criteria for a trial of PSFS 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 PSFS 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 peripheral subcutaneous field stimulation include lead migration or breakage and infection of the lead or neurostimulator.

Clinical Context and Therapy Purpose

The purpose of peripheral subcutaneous 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.

Populations

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

Interventions
The therapy being considered is peripheral subcutaneous field stimulation (PSFS). 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.

Comparators
The following therapies are currently being used to make decisions about peripheral subcutaneous field stimulation (PSFS): pharmacotherapy, exercise or physical therapy, and cognitive-behavioral therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (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.

Review of Evidence

Systematic Reviews
There were no systematic reviews identified evaluating the use of peripheral subcutaneous field stimulation (PSFS) for the treatment of chronic pain.

Randomized Controlled Trials
In 2013, McRoberts et. al. reported on a prospective, randomized, controlled, crossover study in two phases regarding the safety and efficacy of peripheral nerve field stimulation for the management of localized chronic intractable back pain. During phase I, patients rotated through four stimulation groups (minimal, subthreshold, low frequency, and standard stimulation). If a 50% reduction in pain was achieved during any of the three active stimulation groups (responder), the patient proceeded to phase II, which began with implant of the permanent system and lasted 52 weeks. The primary endpoint was a reduction in pain, assessed by the visual analog scale (VAS). Analysis of variance, including the effects of patient, treatment, and study period, was used for phase I results. Phase II results were analyzed by paired t-tests. A total of 44 patients were enrolled at five sites. Of these patients, 32 were implanted with a trial system and 30 completed phase I. During phase I, there were significant differences in mean VAS scores between minimal stimulation and subthreshold stimulation ($p = 0.003$), low frequency stimulation ($p < 0.001$), and standard stimulation ($p < 0.001$). Twenty-four patients were classified as responders to the therapy, and 23 patients received permanent system placement. Significant differences in VAS scores were observed between baseline and all follow-up visits during phase II ($p < 0.001$). This trial did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study.

In 2021, Johnson et. al. 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. 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 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.

Nonrandomized Comparative Study

In 2011, Mironer et. al. assessed the efficacy of interaction between spinal cord stimulation (SCS) and peripheral nerve field stimulation (PNFS) and to evaluate a new spinal-peripheral neuromodulation method for low back pain. This study was a prospective two-part study that included patients with low back pain due to failed back surgery syndrome and/or spinal stenosis. In the first part 20 patients were implanted with SCS and PNFS. They selected the best program out of three: SCS alone, PNFS alone, or both together. In the second part another 20 patients with the same implanted leads were selecting between three programs: SCS and PNFS separately, SCS as anode and PNFS as cathode, or in reverse. In the first part 79% of the patients selected simultaneous use of SCS and PNFS. The overall success of the trials was 85%. In the second part communication between SCS and PNFS provided wider coverage of axial pain. The overall success of the trials was 90%.

Case Series

Sator-Katzenschlager et. al. (2010) reported on a multi-center retrospective study of subcutaneous target stimulation (STS), for the treatment of chronic focal noncancer pain in 111 patients. STS applies permanent electrical stimulation directly at the painful area via a percutaneous-placed subcutaneous lead. The indications for STS were low back pain (n = 29) and failed back surgery syndrome (back pain with leg pain) (n = 37), cervical neck pain (n = 15), and post-herpetic neuralgia (n = 12). Pain intensity was measured on a numerical rating scale (NRS) before and after implantation. Data on analgesic medication, stimulation systems, position, and type of leads and complications were obtained from the patients' records. After implantation, the mean pain intensity improved by more than 50% (mean NRS reduction from 8.2 to 4.0) in the entire patient group (P = 0.0009). This was accompanied by a sustained reduction in demand for analgesics. In all the patients, the STS leads were positioned directly at the site of maximum pain. Lead dislocation occurred in 14 patients (13%), infections in 7 (6%), and in 6 cases (5%), lead fractures were observed. The authors concluded, the retrospective

data analysis revealed that STS effectively provided pain relief in patients suffering from refractory focal chronic noncancer pain and that STS is an alternative treatment option. However, prospective controlled studies are required to confirm these retrospective findings.

Yakovlev et. al. (2010) presented a case report describing the application of peripheral subcutaneous field stimulation (PSFS) to a patient with chronic intractable atypical facial pain when conventional treatment failed to alleviate the pain. The patient underwent a trial of PSFS of two temporary eight electrode leads placed subdermally over the left mandible. After experiencing pain relief over the next two days, the patient was implanted with permanent leads and rechargeable generator two and a half weeks later and reported sustained pain relief at 12-month follow-up visit. The authors concluded; peripheral subcutaneous field stimulation offers an alternative treatment option to select patient with intractable atypical facial pain.

In 2010, Yakovlev et. al. reported on retrospective case series evaluating the efficacy of peripheral nerve field stimulation for the treatment of chronic hip pain after total hip arthroplasty (THA) and greater trochanteric bursectomy (GTB). Twelve patients with chronic post-operative pain after THA and GTB underwent an uneventful PNFS trial with percutaneous placement of 2 temporary 8-electrode leads positioned in the subcutaneous tissue in the area of greatest pain, parallel to postoperative scar over the affected upper lateral thigh. After experiencing excellent pain relief over the next 2 days, the patients were implanted with permanent leads and rechargeable or non-rechargeable generator 2-4 weeks later. They reported sustained pain relief at 12-month follow-up visits.

Verrills et. al. (2011) reported on a prospective, observational study of 100 patients receiving peripheral nerve field stimulation (PNFS) for the treatment of chronic craniofacial (n=40), thorax (n=8), lumbosacral (n=44), abdominal (n=3), pelvic and groin pain conditions (n=5). 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. Outcome measures included pain (11-point numerical rating scale), complications, changes to analgesic use and employment status, disability (Oswestry or Neck Disability Indexes), depression (Zung Depression Index), and patient satisfaction. The results demonstrated an average pain reduction of 4.2 ± 2.5 pain scale points on an 11-point scale following PNFS (preimplant pain score of 7.4 ± 1.7 to a follow-up average of 3.2 ± 2.3 pain scale points) ($P \leq 0.00$). At a follow-up period of 8.1 ± 4.7 months (range 1-23 months), an overall 72% of patients reduced their analgesic use following PNFS. Patients receiving a lumbosacral PNFS for chronic low back pain reported a significant reduction in disability following treatment, as determined by the Oswestry Disability Index. Of the 100 cases, no long-term complications were reported.

Goroszeniuk et. al. (2012) reported on preliminary case reports on an alternative approach to neuromodulation of angina pain using subcutaneous target stimulation-peripheral subcutaneous field stimulation leads placed at the site of pain. In this case series, five patients with refractory angina received successful treatment with subcutaneous target stimulation-peripheral subcutaneous field stimulation. This technique was able to provide good analgesia in two patients that had had poor pain relief from existing spinal cord stimulators. All five patients achieved significant pain relief with a reduction in symptoms and a decrease in the use of pain medication.

In 2012, Burgher et. al. reported on a retrospective review and review of the literature regarding subcutaneous peripheral nerve stimulation with inter-lead stimulation for axial neck and low back pain. Patients proceeding to implant were followed postoperatively with routine clinical visits and a survey form at last follow-up. Ultrasound was used intraoperatively to ensure placement of electrodes at the appropriate depth in patients with larger body mass index. Primary outcome was patient-reported pain relief at last follow-up. Literature review was conducted by searching MEDLINE (1948-present) and through an unstructured review by the authors. Ten patients underwent trial of SQ PNS (subcutaneous peripheral nerve stimulation) and six proceeded to permanent implantation. Fifty percent (3/6) of implanted patients preferred neurostimulation programming that included inter-lead stimulation ("cross-talk"). Average duration of postoperative follow-up was 4.5 months (range 2-9 months). Average patient-reported pain relief at last follow-up was 45% (range 20-80%). One patient required re-operation for migration. Patients not proceeding to implant had paresthesia coverage but no analgesia. The authors concluded, SQ PNS is promising therapy for axial neck and back pain based on a small cohort of patients. While inter-lead stimulation has been preferred by patients in published reports, we did not find it clearly influenced pain relief. Further investigations should include randomized, controlled study design, as well as defined implantation technique and neurostimulator programming algorithms.

In 2014, Kloimstein et. al. reported on a prospective, multicenter observational study of 118 patients to evaluate the safety and efficacy of peripheral nerve field stimulation (PNFS) for chronic low back pain. all patients underwent a trial stimulation period of at least seven days before implantation of the permanent system. Leads were placed in the subcutaneous tissues of the lower back directly in the region of greatest pain. One hundred five patients were implanted with a permanent stimulating system. Patients' evaluation of pain and functional levels were completed before implantation and one, three, and six months after implantation. Adverse events, medication usage, and coverage of the painful area and predictive value of transcutaneous electrical nerve stimulation (TENS) were monitored. All pain and quality-of-life measures showed statistically significant improvement during the treatment period. These included the average pain visual analog scale, the Oswestry Disability Questionnaire, the Becks Depression Inventory, and the Short Form-12 item Health survey. Additionally, medication usage with opioids, nonsteroidal anti-inflammatory drugs, and anti-convulsants showed a highly significant reduction. Complications requiring surgical intervention were reported in

9.6% of the patients. The degree of coverage of painful areas seems to be an important criterion for efficacy of PNFS, whereas TENS is presumably no predictor.

Verrills et. al. (2014) evaluated the efficacy of peripheral nerve field stimulation (PNFS) for the treatment of chronic headache conditions. For more than a four-year period, 83 patients underwent a trial of a PNFS system targeting the nerve regions including occipital and supraorbital and infraorbital nerves, which best corresponded with their area of head pain. Sixty patients reported a successful trial and underwent a subsequent implant of the PNFS system. Questionnaires, along with patients' charts, were used to assess outcomes as follows: pain (11-point numerical pain rating scale), analgesic use, depression (Zung Depression Scale), disability (Neck Disability Index), patient satisfaction, and surgical complications. Patients were followed up for an average of 12.9 ± 9.4 months (range 3-42 months). An average pain reduction of 4.8 ± 2.3 pain scale points was observed (preimplant 7.4 ± 1.6; follow-up 2.6 ± 2.1 [$p \leq 0.001$]). Of the 60 patients implanted, 41 reported >50% pain relief. Medication use was reduced in 83% of patients who were previously taking analgesics or prophylactic medications. Similarly, reductions in degree of disability and depression also were observed. Of the 60 cases, ten surgical revisions were required; however, no long-term complications were reported.

In 2020, Stabingas et. al. reported on a case series and five- year follow-up of peripheral subcutaneous field stimulation for the treatment of spinal cord injury at-level pain. Spinal cord injury (SCI) frequently engenders chronic pain which may be classified as occurring above, at, or below the level of injury. Since patients with SCI may have a complex combination of nociceptive and neuropathic pain, pharmacological interventions often fail. Peripheral subcutaneous field stimulation (PSFS) is a novel neuromodulation surgery for pain in which subcutaneous electrodes designed for spinal cord stimulation are placed subcutaneously in a region of pain. We report the case of a 26-year-old man who was an unrestrained driver in a motor vehicle accident and suffered a complete ASIA A spinal cord injury with paraplegia due to a T4 three-column burst fracture. He underwent successful surgical fixation of the fracture (7/27/12) and developed severe at-level SCI-associated pain which failed all conservative measures. After a successful trial, two octrode leads (Abbott Medical, Plano, TX, USA) were placed for PSFS under general anesthesia and were connected to a right flank rechargeable pulse generator (11/6/13). At 60 months postoperative, the patient continues to use the peripheral field stimulation system on a daily basis and reports near complete relief of his at-level spinal cord injury pain. He noted instantaneous relief of his pain once ideal stimulation programming was achieved and has tolerated complete cessation of all narcotic use. His current programming settings are: Frequency of 50 Hz (Hz), Pulse Width of 350 μs (μsec), Amplitude of 0.00 miliamps (mA), Comf of 7.70 mA, and Perc of 4.50 mA. Chronic pain is a challenging and expensive sequela to manage in SCI patients and newer therapies are needed. Our case suggests that SCI at-level pain may respond durably to PSFS and provides the longest published follow-up on a case of PSFS. Peripheral subcutaneous field stimulation remains an investigational treatment for chronic pain syndrome and larger, long-term follow up studies are needed for the FDA and payers to approve this modality.

Warner et. al. (2020) reported on adults undergoing peripheral nerve stimulation implantation at an academic medical center. 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 subcutaneous field stimulation (PSFS), the evidence includes randomized controlled trials, a nonrandomized comparative study and case series. The randomized controlled trial (RCT) McRoberts et. al. 2013 which used crossover design, did not compare peripheral subcutaneous field stimulation (PSFS) with alternative treatment modalities. Rather, it compared different methods of peripheral subcutaneous field stimulation (PSFS). Among trial participants, 24 (80%) of 30 patients had at least a 50% reduction in pain with any of type of peripheral subcutaneous field stimulation (PSFS). However, because the randomized controlled trial 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. Case series are insufficient to evaluate patient outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Prospective controlled trials comparing peripheral subcutaneous field stimulation (PSFS) with placebo or alternative treatment modalities are needed to determine the efficacy of peripheral subcutaneous field stimulation (PSFS) for chronic pain as either a stand-alone procedure or adjunct therapy with spinal cord stimulation (SCS) for chronic neuropathic pain. Therefore, the evidence is insufficient to determine the effects of the technology on net health outcomes.

Practice Guidelines and Position Statements

Currently there are no evidence based clinical practice guidelines that recommend the use of peripheral subcutaneous field stimulation (PSFS) (also known as peripheral nerve field stimulation (PNFS) or target field stimulation) for the treatment of chronic neuropathic pain.

Regulatory Status

Device	Notice Date	Indication
SPRINT® PNS System	January 22, 2021	Same indication as the original clearance from 2017. Design modifications were made to the system to improve ease of use and reliability of the system.
Sprint® Peripheral Nerve Stimulation (PNS) System	July 2018	Same indications as the original clearance from 2017. Design modifications were made to the system to improve ease of use and reliability of the system.
Sprint® Peripheral Nerve Stimulation (PNS) System	June 26, 2017	The SPRINT Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days 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 • Symptomatic relief of post-operative pain The SPRINT PNS System is not intended to treat pain in the craniofacial region.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies

- 07.01.61 Spinal Cord Stimulation
- 07.01.78 Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain

Peripheral subcutaneous field stimulation (PSFS) (also called peripheral nerve field stimulation (PNFS) or target field stimulation) to include temporary and permanent placement is considered **investigational** for all indications including but not limited to the following because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- Occipital neuralgia
- Chronic headaches/migraines
- Craniofacial pain
- Chronic low back pain
- Chronic thoracic pain
- Chronic neck pain (cervical)
- Chronic shoulder pain to include chronic shoulder pain subsequent to stroke
- Chronic pain following a spinal cord injury
- Inguinal and pelvic pain
- Pain following hernia surgery
- Abdominal pain
- Fibromyalgia
- Post-herpetic pain
- Failed back syndrome or post laminectomy syndrome
- Complex regional pain syndrome Type I or Type II (formerly known as reflex sympathetic dystrophy (RSD))
- Diabetic peripheral neuropathy
- Peripheral vascular disease neuropathy
- Painful peripheral neuropathy
- Intercostal neuralgia
- Radiculopathy
- Lumbosacral arachnoiditis
- Post-thoracotomy syndrome
- Trigeminal neuralgia
- Trigeminal neuropathic pain

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 64999 Unlisted procedure nervous system (when specified as implantation of electrodes or a pulse generator whether for trial or permanent placement of a peripheral subcutaneous field stimulation or target field stimulation)

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POLICY HISTORY

Date	Reason	Action
November 2022	Annual Review	Policy Renewed
November 2021	Annual Review	Policy Renewed
November 2020	Annual Review	Policy Revised
November 2019	Annual Review	Policy Revised
November 2018	Annual Review	Policy Revised
November 2017	Annual Review	Policy Revised
November 2016	Annual Review	Policy Renewed
December 2015		New Policy

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

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