Medical Policy Manual Surgery, Policy No. 205

Implantable Peripheral Nerve Stimulation and Peripheral Subcutaneous Field Stimulation

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Implantable peripheral nerve stimulation (PNS) for chronic pain of *peripheral nerve origin* is a type of neuromodulation therapy that involves the subcutaneous implantation of electrodes near or on a peripheral nerve that is *considered to be the origin of pain*. Peripheral subcutaneous field stimulation (PSFS) is a modification of PNS in which electrodes are implanted subcutaneously within the area of maximal pain with the intent of stimulating the nerves, cutaneous afferents, or the dermatomal distribution of the nerves communicating the pain. These procedures differ from other forms of electrical stimulation because the origin of pain is from a peripheral nerve or nerve field and the electrical impulses are delivered to the nerve or nerve field versus surrounding tissues or the spine.

MEDICAL POLICY CRITERIA

Note: This policy only addresses implantable peripheral nerve stimulation (PNS) and peripheral subcutaneous field stimulation (PSFS) (e.g., StimRouter®, SPRINT®) for chronic pain of peripheral nerve origin. Please refer to the Cross References below for other specific neuromodulation or stimulation therapies.

Implantable peripheral nerve stimulation (PNS) and peripheral subcutaneous field stimulation (PSFS) for pain of peripheral nerve origin is considered **investigational** for all indications, including but not limited to chronic, postoperative, and post-traumatic pain.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Peripheral nerve stimulation (PNS) systems vary from other electrical stimulation therapies.

- Transcutaneous electrical nerve stimulation (TENS) delivers impulses across the skin to alleviate pain. PNS is similar to TENS, except PNS requires electrodes to be inserted under the skin and targets a nerve considered to be the origin of the pain.
- Percutaneous neuromodulation therapy (PNT) is an electrical stimulation therapy in which fine filament electrodes are temporarily placed in the tissues near the area causing pain. PNS is similar to PNT, except PNS requires electrodes to be inserted under the skin and targets a nerve considered to be the origin of the pain.
- Occipital nerve stimulation (ONS) is related to PNS in that a subcutaneous electrode delivers stimulation to the occipital nerve in an attempt to prevent migraines and other headaches in patients who have not responded to medications.

CROSS REFERENCES

1. Percutaneous Neuromodulation Therapy (PNT) and Percutaneous Electrical Nerve Stimulation (PENS), Surgery, Policy No. 44
2. Spinal Cord and Dorsal Root Ganglion Stimulation, Surgery, Policy No. 45
3. Deep Brain Stimulation, Surgery, Policy No. 84
4. Occipital Nerve Stimulation, Surgery, Policy No. 174

BACKGROUND

Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation that delivers electrical impulses *directly to a nerve*.

Implantable PNS therapies have been around since the 1960s.[1] There are several implantable PNS neuromodulation therapies that use electrical stimulation for pain.[2] Examples include, but are not limited to: occipital nerve stimulation (ONS) and spinal cord stimulation (SCS).The StimRouter®, an implantable PNS system, is being marketed specifically for chronic pain *of peripheral nerve origin* i.e. upper/lower limb pain, entrapment syndromes, intercostal neuralgias and other peripheral injuries or diseases.[3] Although SCS addresses pain in the trunk and limbs, the electrodes for SCS deliver electrical stimulation to the spine versus directly to the peripheral nerve pain site like the StimRouter®.[4] The SPRINT® Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) has been cleared for marketing for symptomatic relief of chronic pain, post-surgical, and post-traumatic pain of the back and extremities.[5]

PNS systems include a neurostimulator (pulse generator), leads (thin wires with electrodes), a controller (device that allows the patient to control the device), and a programmer that allows a medical professional to make adjustments to the settings of the pulse generator. The leads are subcutaneously positioned and connected to the generator but the electrodes are not permanently implanted as in spinal cord stimulation. For example, the SPRINT® Peripheral

Nerve Stimulation System is indicated for up to 60 days. A trial of PNS is indicated prior to permanent implantation of the generator. If the trial is successful (defined as greater than 50% response rate in pain reduction), the generator is permanently implanted in the chest, abdomen or buttocks.

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

REGULATORY STATUS

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).[5] The SPRINT® PNS System is not intended to treat pain in the craniofacial region. The Bioness StimRouter® Neuromodulation System received FDA 510(k) approval in February 2015,[6] October 2019,[7] and March of 2020.[8] The StimRouter® is not intended to treat pain in the craniofacial region

In March of 2016, the StimQ Peripheral Nerve Stimulator (PNS) System received FDA 510(k) approval.[9] The StimQ PNS System is not intended to treat pain in the craniofacial region.

No device has been approved specifically for peripheral subcutaneous field stimulation (PSFS) by the U.S. Food and Drug Administration (FDA). PSFS is an off-label use of spinal cord stimulation devices or peripheral nerve stimulation devices (e.g. the SPRINT® PNS System) that have been FDA approved for the treatment of pain.

EVIDENCE SUMMARY

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain can be a subjective outcome associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect and determine if an implanted peripheral nerve stimulation (PNS) system provides a significant advantage over placebo.

Treatment with an implanted PNS system must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an implanted PNS system should be compared to other forms of conservative therapy such as rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

IMPLANTED PERIPHERAL NERVE STIMULATION

Systematic Reviews

Ni (2021) published a systematic review with meta-analysis of 13 studies (n=221) in which PNS was evaluated for the treatment of trigeminal neuropathic pain (TNP).[10] Eleven of the 13 studies examined effects of peripheral neuromodulation for TNP. Intractable facial pain of at least six monthswas an inclusion criterion for all studies, except for one study which evaluated temporary PNS for the treatment of TNP caused by *herpes zoster ophthalmicus*. Ten of 13 (76.9%) studies reported response rates (pain reduction over 50%) as the clinical measurement during follow-up and visual analog scale (VAS) scores were available pre- and post-treatment in eight studies (n=110). The overall estimated response rate was 60.2% (95% CI: 41.9 to 76.1%, I^2=70.733%, p<0.0001), and the mean pain scores were significantly lower at follow-up compared to baseline (standard difference 2.363; 95% CI: 1.408 to 3.319, I^2=85.723%, p<0.0001). Sub-analysis was conducted to evaluate outcomes by target site of stimulation. In the three studies targeting the Gasserian ganglion for facial pain, the overall response rate was 29.3% (95% CI: 19.2 to41.8%, I^2=0, =0.635) and in studies using peripheral branch stimulation, 77.6% of patients reported over 50% pain relief (p<0.0001). Study quality review revealed most studies did not provide sufficient information to evaluate whether outcomes assessment was adequately blinded. None of the included studies provided adequate information on sample size justification, power description, or variance and effect estimates. Improper location of electrodes, infection, and electrode defects were the most common complications. The authors concluded that “randomized, controlled, prospective studies are needed to further compare the clinical efficiency of PNS with other conventional treatments for TNP.”

Randomized Controlled Trials

Ilfeld (2021) published the results of a randomized controlled pilot study of PNS for the treatment of acute postoperative pain.[11] In this study, an electrical lead was percutaneously implanted preoperatively to target the sciatic nerve for major foot/ankle surgery (e.g., hallux valgus correction), the femoral nerve for anterior cruciate ligament reconstruction, or the brachial plexus for rotator cuff repair, followed by a single injection of long-acting local anesthetic along the same nerve/plexus. Postoperatively, participants were randomized to 14 days of either electrical stimulation (n=32) or sham stimulation (n=34). Coprimary outcome measures were cumulative opioid consumption and mean average daily pain scores on a 0 to 10 Numeric Rating Scale within the first seven postoperative days. The authors found opioid use in the active stimulation group was a median (interquartile range) of 5 mg (0 to 30) and 48 mg (25 to 90) in the sham treatment group (ratio of geometric means, 0.20 [97.5% CI, 0.07 to 0.57]; p<0.001). The average pain intensity in the active stimulation group was (mean ± SD) 1.1 ± 1.1 and 3.1 ± 1.7 in the sham group (difference, −1.8 [97.5% CI, −2.6 to −0.9]; p<0.001). This pilot study is severely limited by the short follow-up time of seven days, precluding evaluation of mid- or longer-term safety and effectiveness of the intervention. A larger, longer-term randomized controlled trial is anticipated.

In an industry-sponsored randomized controlled trial (RCT) published by Gilmore (2019), 28 lower-extremity amputees with postamputation pain were randomized to PNS or placebo for four weeks.[12] A significantly greater proportion of subjects receiving peripheral nerve stimulation (PNS) (n=7/12, 58%, p=0.037) demonstrated ≥50% reductions in average postamputation pain up to four weeks compared with subjects receiving placebo (n=2/14, 14%). In addition, a significantly greater proportion of PNS subjects reported ≥50% reductions in pain and pain interference after eight weeks of therapy compared with subjects receiving placebo, however the partial crossover design of this study prevents evaluation of placebo effects beyond four weeks. Twelve-month follow-up is ongoing. Overall, the study is limited by a small sample size which limits generalizability.

The results of an RCT of PNS compared to usual care (UC) for hemiplegic shoulder pain was published by Wilson (2016).[13] The study included 25 participants (12 PNS and 12 UC).

Although pain reduction with PNS treatment group was reported as significantly greater than the UC group, the per-protocol analysis of 21 participants showed significant reductions in pain in both groups and no significant slope difference between groups during the study. In addition, no significant group differences were observed for secondary outcome measures including pain interference, physical functioning, and global success rates. The authors concluded that additional RCTs are needed to determine treatment effectiveness.

Deer (2015) published a multicenter, randomized, double-blinded, partial crossover study addressing the safety and efficacy of the StimRouter® neuromodulation system for 94 patients with chronic pain of peripheral nerve origin (upper or lower extremity or trunk).[14] The patients were assigned to the StimRouter® group (n=45) or the control group (n=49). Efficacy was evaluated for three months and safety for one year. Primary outcomes included pain relief and safety. At three months the StimRouter® group reported 27.2% pain reduction vs. the control group 2.3%. Fifty-one percent of patients did not follow-up at one year. No serious adverse events were reported related to the device. A significant limitation of the study is the small sample size and large loss to follow-up.

Nonrandomized Studies

Warner (2020) published a retrospective case series of 72 patients who had undergone PNS implantation for treatment of various indications including occipital neuralgia (47%) and lower-extremity neuropathies (17%).[15] Six-month outcomes were assessed by numerical rating scale pain scores, opioid utilization, and self-reported functioning. Infection and device-related complications were also assessed. PNS implantation was associated with reductions in pain scores ($p<0.001$) and opioid utilization ($p<0.001$). Postoperative surgical site infection was found in ten percent of patients leading to device removal in five patients. No comparison to standard of care was provided.

A retrospective chart review including data from 240 patients implanted with a PNS, 165 of whom were being treated for complex regional pain syndrome, was published by Chmiela in 2020.[16] Median length of follow-up was 74 months. Pain scores at 12-month follow-up were decreased by an estimated 1.87 points (95% CI: [1.29, 2.46], paired t-test $p<0.001$). The percentage of patients on chronic opioid therapy decreased over 12 months from 62% to 41%. Of the 126 patients who reported changes in functional status, 64 (51%) reported improvement, 27 (21%) reported worsening, and 35 (28%) did not report any meaningful change. Excluding end-of-life battery replacements, surgical revision was needed in 56 (34%) of patients. Thirteen patients (8%) underwent implantation of a second PNS due to symptomatic expansion outside of the original region and device explant was performed in 32 (19%) of patients.

A multi-center, prospective case series published by Oswald (2019) evaluated outcomes in 39 patients implanted with the StimRouter™ on various isolated mononeuropathies.[17] The authors report 78% of the participants noted an improvement in pain, 72% noted improvement in activity, and 89% experienced a greater than 50% reduction in opioid consumption. This was not a controlled trial and no information comparing these outcomes to outcomes achieved through standard of care was provided. Future RCTs addressing these limitations are required.

Ilfeld (2017) published a review evaluating the safety of lead types in clinical studies of percutaneous neurostimulation of the peripheral nervous system.[18] Forty-three studies were included and of these both coiled (n=21) and noncoiled (n=25) leads were studied. The infection rates were estimated to be 0.03 (95% CI 0.01 to 0.13) infections per 1,000 indwelling days for coiled leads and 0.83 (95% CI 0.16 to 4.33) infections per 1,000 indwelling days for noncoiled leads. No information is provided in the publication regarding clinical outcomes other than infection rates and no control group is evaluated.

Deer and Rosenfeld (2010) published the results of a single-center open-label study in which eight patients with carpal tunnel syndrome were evaluated for pain relief from the StimRouter™.[19] Pain evaluation occurred before implant, during implant and after explant. The authors concluded the StimRouter™ was effective and safe for pain reduction from carpal tunnel syndrome, but the study had methodological limitations including a small sample size and no mention of follow-up after the StimRouter™ was explanted after five days of treatment.

Numerous additional case series and case studies have been published on PNS for the treatment of conditions including complex regional pain syndrome,[20] chronic shoulder pain,[21] chronic low back pain,[22] peripheral neuralgia,[23] oncologic pain,[24] and trigeminal pain.[25] Case studies and small case series generally are not considered in evidence reviews as they do not provide sufficient sample sizes or comparison groups to determine the added benefit of the technology on health outcomes over standard of care for any patient population.

PERIPHERAL SUBCUTANEOUS FIELD STIMULATION

Systematic Review

Sarica (2022) published the results of a systematic review with meta-analysis of studies reporting pain outcomes (visual analogue scale [VAS]) in patients treated with peripheral nerve field stimulation for facial pain, with a focus on trigeminal nerve pain.[26] Data from 11 observational, single-site cohort studies (n=109) were included in the review, five of which were prospective. Nine studies included cohorts of mixed diagnoses, and the most common diagnoses were persistent idiopathic facial pain (PIFP; n=26) and trigeminal neuropathic pain (TNP; n=25), followed by postherpetic neuralgia (PHN; n=19), symptomatic trigeminal neuralgia (STN; n=14), trigeminal neuralgia type 2 (TN2; n=12) and type 1 (TN1; n=8), and trigeminal deafferentation pain (TDP; n=5). The number of patients included in each study ranged from 7 to 19. Common previously trialed interventions included nerve blocks (56%, 37/66), microvascular decompression (MVD; 25%, 16/65), percutaneous gasserian ganglion procedures (PGPs; 18%, 10/57), and stereotactic radiosurgery (SRS; 7%, 4/57). Nine trials included pre-implantation trial of temporary lead placement, one trial used adhesive electrodes and one used nerve block injections. The mean study follow-up period ranged from one month to 63.7 months. Analysis of individual patient data available for 62 patients from eight studies found mean improvement in VAS pain score at last follow-up to be 6.3 (95% CI 5.5–7.1, paired t-test, $p < 0.001$), with 79% (49/62) having a postoperative pain score less than 5. A total of 51 complications occurred across 105 implantation surgeries in 44 patients (49% per procedure). The rate of complications requiring a surgical intervention was 32% per procedure (range 0% to 82% across studies). The most frequent complications that required surgical management were skin erosions (n=13) and infection (n=10). The risk of bias of the included studies ranged from 4 to 6 out of a possible 6 stars when assessed using the Newcastle-Ottawa Scale and statistical heterogeneity was considerable (I^2=79%) across all studies. Although evidence of publication bias was not found (Egger's test, p=0.20), significant small-study effects were found; 4 of the 11 studies fell outside of the 95% CI of the effect summary estimate for pain reduction outcome. The considerable heterogeneity across studies with respect to follow-up periods, rating scales used, patient selection/trial methods, stimulation parameters and preoperative conditions, as well as small sample sizes and lack of controlled/comparator groups are limitations to the available evidence regarding peripheral nerve field stimulation for the treatment of facial pain.

A systematic review (SR) by Hofmeister (2020) evaluating the effectiveness of neurostimulation technologies for the management of chronic pain included one study on peripheral subcutaneous field stimulation (PSFS).[27] This study (Eldabe 2018) is discussed below.[28]

Randomized Controlled Trials

Albright-Trainer (2022) conducted a randomized controlled feasibility trial of PNS for the management of post-amputation pain.[29] 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 three individuals in the PNS group and one individual in the control group. 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.

Ilfeld (2021) published the results of a randomized, sham-controlled, pilot study of PNS for the treatment of postoperative pain in individuals receiving foot, ankle, knee, or shoulder surgery. 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 seven 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<0.001) and average pain intensity of 1.1 versus 3.1 (difference in means, -1.8; 97.5% CI, -2.6 to -0.9; p<0.001) 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.

Van Gorp (2019) published the 12-month follow-up of a multicenter RCT of patients with chronic low back pain in failed back surgery syndrome (FBSS) treated with spinal cord stimulation (SCS) alone and SCS with peripheral subcutaneous nerve field stimulation (PSFS).[28] Although the initial RCT randomized patients to treatment (SCS with PSFS) or control (SCS alone),[30] after the three-month study period, all patients in both groups received optimal SCS with PSFS during the open follow-up for the duration of the subsequent nine months. Thus, for the analysis of the follow-up data, both groups were combined and data from all patients at 12 months (n=50) were compared to their own baseline values. Back pain, measured on a 100-mm visual analog scale (VAS), significantly decreased by 30.0 mm (95% CI: 237.7/222.4]; p<0.001), and leg pain decreased by 43.7 mm (95% CI: [251.5/236.2]; p<0.001). The authors also reported significant improvements across the 50 participants on secondary outcome measures including physical functioning, disability, pain, social functioning, anxiety, and medication indices. While this prospective, multicenter study provides valuable data on the efficacy of the simultaneous use of SCS and PSFS in a homogeneous, highly selected group of FBSS patients, the data do not permit conclusions regarding the added benefit of PSFS over SCS alone or the added benefit of this technology in other clinical populations. Additional long-term RCTs evaluating the added benefit of PSFS on health outcomes are needed.

Eldabe (2018) published a multi-site (21 sites) RCT comparing the effectiveness of subcutaneous peripheral nerve (field) stimulation (SQS) plus optimized medical management (SQS + OMM arm) compared to optimized medical management alone (OMM arm) in patients with back pain due to failed back surgery syndrome (FBSS).[31] Those in the SQS arm were implanted with a neurostimulator and up to two subcutaneous percutaneous cylindrical leads in the area of pain. Patients were evaluated pre-randomization and at one, three, six, and nine months post-randomization. The primary endpoint was the proportion of subjects with a ≥50% reduction in back pain intensity (“responder”) from baseline to nine months. A total of 33.9% (19/56, missing: n=20 [36%]) of subjects in the SQS + OMM arm and 1.7% (1/60, missing: n=24 [40%]) in the OMM arm were responders at month nine (p<0.0001). Although these results suggest that the addition of SQS to OMM is more effective than OMM alone in relieving low back pain at up to nine months in this study population, due to the slow rate of recruitment, the study was terminated early. Additional appropriately powered RCTs with longer-term follow-up are needed.

One small randomized double-blind crossover trial was published by McRoberts in 2013, however, this study did not include a control group or a comparison group of alternative treatment modalities.[32] The aim of this two-phase study was “to obtain preliminary estimates of the safety and efficacy of PSFS therapy using equipment originally designed for spinal cord stimulation.” In the first phase of the study, patients (n=32) were initially randomized to one of the four stimulation groups, minimal, subthreshold, low frequency, and standard stimulation. Participants then rotated through all four stimulation groups in four to eight-day intervals. Both the investigator and patient were blinded to the group assigned. Two patients exited the study during phase I due to device/procedure-related adverse effects. “Responders” (n=24), defined as patients in any of the three active stimulation groups reporting ≥50% pain reduction, progressed to the second phase of permanent system implant (n=23). One responder did not receive permanent implantation due to non-device/procedure-related adverse effects.

Patients were followed for 52 weeks during which time reported mean visual analog scale (VAS), 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). Excellent or good pain relief was reported in 16 (69.5%) patients at the 52-week follow-up visit. Opioid use decreased in 10 (43%) patients, remained stable in 8 (35%) patients, and increased in 5 (22%) patients. The most common adverse events were diminished or loss of therapy (n=10) and lead migration (n=7). Four patients had their systems explanted prior to completion of the study.

This study had a number of significant limitations that precluded conclusions, including but not limited to the small number of patients and the lack of an appropriate control group. Because this study did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study. Further data are needed from well-designed RCTs which include large sample sizes and an appropriate control group for comparison.

NONRANDOMIZED TRIALS

Kloimstein (2014) reported on a prospective study of 118 patients treated with PSFS for chronic low back pain.[33] Before patients were implanted with the permanent PSFS system, a trial of stimulation was given for at least seven days. The permanent stimulation system was implanted in 105 patients. Significant improvements occurred at one, three, and six months' follow-up after implantation in the average pain VAS, Oswestry Disability Questionnaire, Becks Depression Inventory, and the Short Form-12 health survey. Significant reductions in opioid, nonsteroidal anti-inflammatory and anti-convulsant medications also occurred.

Verrills (2014) reported on PSFS for chronic headache conditions.[34] After a trial stimulation period, 60 patients underwent permanent implantation of the PSFS system and were followed for an average of 12.9 ± 9.4 months (range, 3 to 42 months). Ten patients required revision of the implant system. Significant reductions in pain were reported ($p \leq 0.001$). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients and disability and depression improved.

Verrills (2011) reported on a series of 100 patients treated PSFS for chronic neuropathic pain. Indications included chronic pain in occipital/craniofacial (n=40), lumbosacral (n=44), thoracic (n=8), groin/pelvis (n=5), or abdominal (n=3) regions.[35] 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 were assessed at a mean of 8.1 months after implantation (range, 1-23 months) with a combination of numerical pain scores, patient answered questionnaires, and patient medical histories. For the entire cohort, pain decreased from 7.4 at baseline to 4.2 at follow-up. About 34% of patients had at least a 75% improvement in pain scores and 69% improved by at least 50%. Analgesic use decreased in 40% of patients following PSFS. Adverse events were reported in 14% of patients, including unpleasant sensations, lead erosions and lead or battery migration.

Sator-Katzenschlager (2010) reported a retrospective multicenter study of the use of PSFS.[36] A total of 111 patients with chronic 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% improvement in pain on a numerical rating scale during the trial period. After permanent implantation, pain intensity decreased in 102 patients (92%). Mean pain intensity decreased from 8.2 at baseline to 4.0 at follow-up with a reduction in consumption for analgesics and antidepressants. Lead dislocation or fracture occurred in 20 patients (18%).

PRACTICE GUIDELINE SUMMARY

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. [37] Recommendations for best practices are listed below:

Head and Neck:

- Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average effect size for relief of migraine symptoms is modest to moderate. Level of Evidence (LOE) I. Degree of Recommendation (DOR) B.
- There is presently insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain. LOE: II-3 DOR: 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. LOE: I DOR: 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. LOE: II-2 DOR: 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. LOE: I DOR: B
- There is evidence that peripheral nerve stimulation (PNS) of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain. LOE: II-2 DOR: B
- There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia. LOE: III DOR: 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. LOE: I DOR: 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. LOE:I DOR: B

Complex regional pain syndrome (CRPS)

- As a less-invasive modality compared to spinal cord stimulator (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. LOE: III DOR: 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. LOE: III DOR: I

The National Institute for Health and Care Excellence issued guidance in 2013 on peripheral subcutaneous field stimulation for chronic low back pain.[38] The guidance stated: "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. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

SUMMARY

There is not enough research to show that implantable peripheral nerve stimulation (PNS) or peripheral subcutaneous field stimulation (PSFS) improves health outcomes for any indication, including for the treatment of chronic, postoperative, or post-traumatic pain of peripheral nerve origin. Therefore, the use of an implantable PNS system including peripheral subcutaneous field stimulation (PSFS) for treatment of pain of peripheral nerve origin is considered investigational including but not limited to the treatment of chronic pain, post-operative, or post-traumatic pain.

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CODES

Codes	Number	Description
CPT	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
	64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
	64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
	64999	Unlisted procedure, nervous system
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulsewidth, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	;with simple spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter, t programming by physician or other qualified health care professional
	95972	;with complex spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	C1778	Lead, neurostimulator (implantable)
	C9807	Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8680	Implantable neurostimulator electrode, each

L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8679	Implantable neurostimulator, pulse generator, any type

Date of Origin: *January 2018*