Medical Policy Manual Surgery, Policy No. 205

Implantable Peripheral Nerve Stimulation and Peripheral Subcutaneous Field Stimulation

Effective: November 1, 2026

Next Review: May 2027
Last Review: October 2026

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 is a type of neuromodulation therapy that involves the implantation of electrodes near or on a peripheral nerve. 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 electrodes are implanted and the electrical impulses are delivered directly to the nerve or nerve field versus surrounding tissues or the spine.

MEDICAL POLICY CRITERIA

Notes:

- This policy only addresses implantable peripheral nerve stimulation (PNS) and peripheral subcutaneous field stimulation (PSFS) (e.g., StimRouter®, SPRINT®, ReActiv8®) for chronic pain. Please refer to the Cross References below for other specific neuromodulation or stimulation therapies.

- Member contracts for covered services vary. Specific contract language takes precedence over medical policy, and requests for stimulator revision/removal should be reviewed by applicable member contract language (see member contract language for health interventions related to a non-covered service).

Implantable peripheral nerve stimulation (PNS) and peripheral subcutaneous field stimulation (PSFS) delivered directly to a nerve 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 directly to a nerve.
- 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.
- 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] The ReActiv8® device (Mainstay Medical) is an implantable PNS marketed to restore neuromuscular control and retrain stabilizing muscles (multifidus muscle) for those with mechanical chronic low back pain.[6] 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 or percutaneously 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 June 2020, the ReActiv8® (Mainstay Medical) was FDA approved through the Premarket Approval (PMA) process (PMA P190021) for individuals with intractable mechanical chronic low back pain associated with multifidus dysfunction for whom available low back pain treatments do not provide sufficient or durable symptom relief.[6]

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,[7] October 2019,[8] and March of 2020.[9] 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.[10] 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

Bess (2025) published a systematic review (n=650; 2 RCTs) evaluating restorative neurostimulation in patients with multifidus dysfunction and chronic low back pain.[11] At one year, restorative neurostimulation reduced pain Numerical Rating Scale (NRS) by a mean of 3.2 points, Oswestry Disability Index (ODI) by 16.8 points, and an improvement in health-related quality of life (EQ-5D) of 0.200. At four years, there was a weighted average reduction in NRS pain of 4.1, a 22.7 point reduction in ODI, and an EQ- 5D improvement of 0.251. The only trial with an active comparator was the RESTORE trial (see Schwab 2025 below) which had NRS reduction of 0.5, ODI improvement of 2.9, and EQ-5D improvement of 0.013 at one year.

D'Souza (2025) published a systematic review and meta-analysis examining implantable peripheral nerve stimulation (PNS) for chronic pain.[12] The review included 106 studies comprising 9,272 patients. PNS was associated with large, statistically significant reductions in pain intensity from baseline at all time points: 3 months (Hedges' g = 2.92, 95% CI 2.62 to 3.21), 6 months (Hedges' g = 3.08, 95% CI 2.68 to 3.48), 12 months (Hedges' g = 2.68, 95% CI 2.30 to 3.05), and 24 months (Hedges' g = 2.08, 95% CI 1.68 to 2.48) (all $p < 0.001$). The largest effect sizes were observed in pelvic and upper extremity pain, whereas the smallest were in truncal pain. Study limitations included low certainty of evidence due to pooling from observational studies, risk of bias, and methodological heterogeneity.

Manchikanti (2025) published a systematic review and meta-analysis of randomized controlled trials evaluating peripheral nerve stimulation for chronic pain management.[13] Seven of nine studies demonstrated moderate evidence and clinical applicability, and two of nine showed low evidence and applicability. The combined qualitative and quantitative analysis supported a fair (Level III) evidence level, with moderate certainty and moderate strength of recommendation for implantable PNS systems following a trial or selective lumbar medial branch stimulation without a trial, and temporary PNS therapy for 60 days. The authors noted that the study was limited by a lack of high-quality studies.

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).[14] Eleven of the 13 studies examined effects of peripheral neuromodulation for TNP. Intractable facial pain of at least six months was 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

Hatheway (2026) conducted a multicenter RCT evaluating the safety and efficacy of PNS using the Nalu Neurostimulation System for treating chronic peripheral neuropathic pain in the COMFORT Study (N = 131).[15] Patients were randomized to receive either PNS with conventional medical management (CMM) (n = 58) or CMM alone (n = 31), with 46 and 31 subjects respectively included in the modified intention-to-treat population. At 3 months, the responder rate (≥50% pain reduction) in the PNS with CMM arm compared to the CMM alone arm was statistically significantly higher (84% vs. 3%; p < .001) as well as the pain reduction (67% vs. 6%; p < .001). These results were sustained at 6 months, with an 88% responder rate and 70% pain reduction in the PNS with CMM arm. At 12 months, after patients from the CMM alone arm were given the option to cross over to the PNS with CMM arm after the initial 3 months, 87% of participants (53/61) were responders with a mean pain score reduction from 7.5 ± 1.2 to 2.3 ± 1.7 (p < .001), and 31% were high responders (≥80% pain reduction).[16] There were no serious adverse events. Limitations included the lack of blinding, short control arm duration (3 months), absence of standardized neuropathic pain questionnaires, variability in conventional medical management, a disproportionate number of female participants (70%), and high attrition after randomization.

Schwab (2025) conducted a multicenter, open-label RCT investigating the effect of restorative neurostimulation therapy using the ReActiv8 system compared to optimal medical management (OMM) for treating chronic low back pain (CLBP) due to multifidus dysfunction (n = 203) (RESTORE, NCT04803214).[17] Participants were randomized to either restorative neurostimulation (n = 99) or OMM (n = 104). The primary endpoint was the mean change in the Oswestry Disability Index (ODI) at one year. The results showed a significant improvement in ODI for the treatment arm compared to the control arm (ODI: 19.7 ± 1.4 vs. 2.9 ± 1.4; p < 0.001). Secondary endpoints also showed significant improvements in the numeric rating scale (NRS) in the treatment arm compared to the control arm for pain (3.6 ± 0.2 vs. 0.6 ± 0.2; p < 0.001) and health-related quality of life (EQ-5D-5L) (0.155 ± 0.012 vs. 0.008 ± 0.012; p < 0.001). 72% of patients in the treatment arm reached the composite endpoint of ≥ 15-point ODI improvement and/or ≥50% NRS improvement, compared to 11% in the control arm (p < 0.001). Safety outcomes indicated that 31 device-, procedure-, and/or therapy-related adverse events occurred in 23 (23.2%) patients in the treatment arm, with common events including implant site pocket pain (8.1%), device overstimulation (5.1%), and lead fracture (3.0%). Several limitations were identified. Participants were not blinded which could have led to placebo effects in the treatment arm and nocebo effects in the control arm. The treatment arm received more clinical contact than standard management protocols for restorative neurostimulation therapy which could artificially inflate healthcare utilization in the short term. There was a statistically significant imbalance in baseline depression with more active depression in the control arm than the treatment arm which could bias the effectiveness of treatment.

Smuck (2025) conducted a post-hoc reanalysis of the sham-controlled pivotal trial (ReActiv8-B, n = 204) to evaluate categorical responder rates using common clinically relevant improvement thresholds that were not included in the original trial's analysis plan.[18] Using a complete-case analysis (n = 201 at 120 days), the reanalysis reported statistically significant differences favoring treatment over sham for ODI improvement at the ≥15-point threshold (59.0% vs 40.6%; p = 0.0111) and ≥30% threshold (65.0% vs 47.5%; p = 0.0156), EQ-5D improvement at the ≥0.15-point threshold (57.0% vs 36.0%; p = 0.0045), and subject global impression of change of "better" or more (54.0% vs 33.7%; p = 0.0045). However, categorical pain responder rates on VAS did not differ significantly at the ≥2-point threshold (61.0% vs 49.5%; p = 0.1192) or ≥50% improvement threshold (45.0% vs 35.6%; p = 0.1971), although mean VAS change favored treatment (−3.3 vs −2.4; p = 0.0209). Limitations include, as a post-hoc reanalysis, the outcome thresholds reported were not included in the original trial's prespecified statistical analysis plan, introducing the potential for selective reporting bias. Additionally, the 120-day follow-up may not capture the full treatment effect, and these results do not provide information regarding longer-term outcomes.

Goree (2024) conducted a multicenter, randomized, double-blind, placebo-controlled trial, evaluating the efficacy of a 60-day PNS treatment using the SPRINT PNS System for persistent postoperative pain following total knee arthroplasty (TKA) (N=52).[19] Patients were randomized to receive active PNS (n=20) or sham stimulation (n=21). Results showed a significantly greater proportion of those receiving PNS achieved ≥50% pain relief during weeks 5 to 8 compared to placebo (60% vs. 24%; p=.028), with corresponding improvements in walking ability (+47% vs. -9%; p=.048) and function (The Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] total score improvement: 62% vs. 35%; p=.006). Quality of life also improved more in the PNS group, with 90% reporting benefit (PGIC ≥1) versus 55% in the placebo group (p=.031). The study reported no serious or unanticipated adverse events. Limitations included the small sample size, a high loss to follow-up, and early study termination due to COVID-19-related enrollment challenges.

Gilligan (2021) conducted a multicenter, sham-controlled RCT of 204 patients with chronic, refractory low back pain (ReActiv8-B, NCT02577354). Control group participants received treatment with the ReActiv8 system set to deliver low-level stimulation.[20] The primary endpoint was the difference in proportions of responders in the treatment and control groups. Response was defined as the composite of 30% or greater reduction in VAS and no increase in pain medications, assessed at 120 days. Following the 120-day randomized phase, participants in the control group were given the option to cross over to the intervention group and were followed along with the participants from the intervention group for up to three years. At 120 days, there was no difference between groups on the primary endpoint of treatment response (57.1% intervention vs 46.6% sham; p = 0.1377) or the individual components of the primary endpoint. The study investigators conducted prespecified secondary analyses of the primary outcome data, including the between-group difference in VAS at 120 days, a review of participants with increased pain medications, and a cumulative-proportion-of-responders analysis, which graphically displays the proportion of responders across the range of all possible cutoffs and is described as having greater statistical power than the comparison of proportions of the dichotomized primary outcome. The VAS mean change from baseline to 120 days favored the intervention group (-3.3 vs -2.4; p = 0.032), but it is unclear if the difference between groups (0.9 points) was clinically meaningful. The cumulative proportion-of-responders analysis similarly favored the intervention group (p = 0.0499). Nine participants in both the intervention and control groups had an increase in pain medication at 120 days, but the increase was unrelated to low back pain in six of nine participants in the treatment group

versus zero of nine in the control group. Study limitations include a short-term follow up. In the longer-term, uncontrolled follow-up phase of the trial, there was continued improvement in VAS scores over time in those who were assessed, but the lack of a control group and high attrition limits drawing conclusions from these results. Data was available for 176 of 204 participants at one year (86.3%),[20] 156 of 204 participants (79%) at 2 years,[21] and 130 of 204 (63.7%) at 3 years.[22] Gilligan (2024) reported follow-up at 5 years.[23] A total of 126 patients were included and back pain VAS improved from 7.3 at baseline to 2.3 at 5-year follow-up with 71.8% of participants reporting a reduction of at least 50%. ODI scores and EQ-5D scores were also improved at long-term follow-up.

Ilfeld (2021) published the results of a randomized controlled pilot study of PNS for the treatment of acute postoperative pain.[24] 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.

Gilmore (2019) reported the 12-month results of their study to evaluate the long-term efficacy of a 60-day PNS treatment for chronic post-amputation pain.[25] The active treatment group (Group 1) received 8 weeks of active PNS, while the sham group (Group 2) received 4 weeks of sham stimulation followed by 4 weeks of active PNS in a partial crossover design. After the 8-week treatment period, all leads were removed and both groups were followed monthly for up to 12 months post-initial implantation. At 12 months, the response rate of Group 1 was statistically significantly higher than that of Group 2 at the end of the initial 4-week placebo period (67% vs. 0%; p=.001). Additionally, 56% of the active group reported ≥50% reductions in pain interference, with significant improvements in depression scores (BDI-II) and PGIC. No serious adverse events were reported. Limitations included the small sample size, optional and inconsistently applied lead replacement in the sham group after crossover, lack of time-matched placebo comparisons, and potential bias from missing data imputation.

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.[26] 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. 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).[27] 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).[28] 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

Deckers (2018) published a prospective single-arm trial (ReActiv8-A; NCT01985230) at nine sites in the United Kingdom, Belgium, and Australia to assess technical feasibility, performance, and safety of the ReActiv8 system. Participants were followed at 45, 90, 180, and 270 days, then annually for four years. Results at one year,[29] two years,[30] and four years[31] have been published. Mitchell (2021) published results of a 4-year follow up (n = 33) showing 73% of the participants had a clinically meaningful improvement of two points or greater on the low back pain Numeric Rating Scale and 76% had an improvement of 10 points or greater on the Oswestry Disability Scale.[31]

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%).[32] 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.[33] 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.[34] 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.[35] 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™.[36] 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,[37] chronic shoulder pain,[38] chronic low back pain,[39 40] peripheral neuralgia,[41] oncologic pain,[42] and trigeminal pain.[43] 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.[44] 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 of 66), microvascular decompression (MVD; 25%, 16 of 65), percutaneous gasserian ganglion procedures (PGPs; 18%, 10 of 57), and stereotactic radiosurgery (SRS; 7%, 4 of 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 to 7.1, paired t-test, $p<0.001$), with 79% (49 of 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).[45] This study (Eldabe 2018) is discussed below.[46]

Randomized Controlled Trials

Albright-Trainer (2022) conducted a randomized controlled feasibility trial of PNS for the management of post-amputation pain.[47] 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).[46] Although the initial RCT randomized patients to treatment (SCS with PSFS) or control (SCS alone),[48] 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).[49] 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.[50] 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.[51] 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.[52] 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 ($p\leq0.001$). 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.[53] 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.[54] 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 INTERVENTIONAL PAIN PHYSICIANS

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based guidelines on implantable peripheral nerve stimulation for chronic pain.[55] The guidelines support the use of implantable peripheral nerve stimulation (PNS) systems and temporary 60-day PNS systems in appropriately selected patients with chronic pain refractory to conservative treatment. Both indications received a moderate recommendation based on Level III (fair) evidence with moderate certainty. The guidelines also recommend consideration of PNS for craniofacial pain, phantom limb pain, and nociceptive low back pain.

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.[56] 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.[57] 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. Therefore, the use of an implantable PNS system including peripheral subcutaneous field stimulation (PSFS) delivered directly to a nerve for treatment of pain is considered investigational including but not limited to the treatment of chronic pain, post-operative, or post-traumatic pain.

REFERENCES

1. International Neuromodulation Society: Peripheral Nerve Stimulation. Secondary International Neuromodulation Society: Peripheral Nerve Stimulation [cited 6/25/2026]. 'Available from:' http://www.neuromodulation.com/PNS.

2. International Neuromodulation Society: Neuromodulation Therapies - Patient Information. Secondary International Neuromodulation Society: Neuromodulation Therapies - Patient Information [cited 6/25/2026]. 'Available from:' http://www.neuromodulation.com/therapies.
3. Bioness. StimRouter. Secondary StimRouter [cited 6/25/2026]. 'Available from:' http://stimrouter.com/.
4. Bioness. Control Your Pain, Live Your Life. Secondary Control Your Pain, Live Your Life [cited 6/25/2026]. 'Available from:' http://www.stimrouter.com/dtcinquiries/?utm_source=PPC&utm_medium=Ads&utm_campaign=WP_StimRouter_Brand&gclid=EAIaIQobChMI5Nf3y_H61gIVwSWBCh0C6A8JEAAYASAAEgLRRfD_BwE.
5. The US Food and Drug Administration: SPRINT Peripheral Nerve Stimulation System (K181422). Secondary The US Food and Drug Administration: SPRINT Peripheral Nerve Stimulation System (K181422) [cited 6/25/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf.
6. Medical M. ReActiv8 Restorative Neurostimulation. Secondary ReActiv8 Restorative Neurostimulation [cited 10/1/2026]. 'Available from:' https://mainstaymedical.com/.
7. United Stated Food and Drug Administration (FDA): StimRouter Neuromodulation System. Secondary United Stated Food and Drug Administration (FDA): StimRouter Neuromodulation System [cited 6/25/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142432.pdf.
8. United Stated Food and Drug Administration (FDA): StimRouter Neuromodulation System. Secondary United Stated Food and Drug Administration (FDA): StimRouter Neuromodulation System [cited 6/25/2026]. 'Available from:' https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K190047.
9. United Stated Food and Drug Administration (FDA): StimRouter Neuromodulation System. Secondary United Stated Food and Drug Administration (FDA): StimRouter Neuromodulation System [cited 6/25/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200482.pdf.
10. United Stated Food and Drug Administration (FDA): StimQ Peripheral Nerve Stimulator (PNS) System. Secondary United Stated Food and Drug Administration (FDA): StimQ Peripheral Nerve Stimulator (PNS) System [cited 6/25/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf15/K152178.pdf.
11. Bess S, Lafage V, Lorio M, et al. Multifidus Dysfunction and Chronic Low Back Pain: Systematic Review and Meta-analysis of the Supporting Data for Accurate Diagnosis and Successful Treatment Outcomes Associated With Restorative Neurostimulation. *Int J Spine Surg.* 2025;19(S3):S67-s84. PMID: 41224648
12. D'Souza RS, Her YF, Morsi M, et al. Implantable peripheral nerve stimulation for chronic pain: a systematic review and meta-analysis of analgesic outcomes up to 24 months. *Reg Anesth Pain Med.* 2025. PMID: 41193385
13. Manchikanti L, Khaira MB, Soin A, et al. Effectiveness of Peripheral Nerve Stimulation in Managing Chronic Pain: A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Pain Physician.* 2025;28(5):E481-e507. PMID: 40986902
14. Ni Y, Yang L, Han R, et al. Implantable Peripheral Nerve Stimulation for Trigeminal Neuropathic Pain: A Systematic Review and Meta-Analysis. *Neuromodulation : journal of the International Neuromodulation Society.* 2021. PMID: 34008282
15. Hatheway J, Hersel A, Engle M, et al. Clinical study of a micro-implantable pulse generator for the treatment of peripheral neuropathic pain: 12-month results from the

COMFORT-randomized controlled trial. *Reg Anesth Pain Med.* 2026;51(3):278-84. PMID: 39572166
16. Hatheway J, Hersel A, Song J, et al. Clinical study of a micro-implantable pulse generator for the treatment of peripheral neuropathic pain: 3-month and 6-month results from the COMFORT-randomised controlled trial. *Reg Anesth Pain Med.* 2025;50(7):561-67. PMID: 38821535
17. Schwab F, Mekhail N, Patel KV, et al. Restorative Neurostimulation Therapy Compared to Optimal Medical Management: A Randomized Evaluation (RESTORE) for the Treatment of Chronic Mechanical Low Back Pain due to Multifidus Dysfunction. *Pain Ther.* 2025;14(1):401-23. PMID: 39812968
18. Smuck M, Lukes D, Schneider B, et al. Reevaluation of categorial outcomes using common clinically relevant improvement thresholds following bilateral L2 medial branch restorative neurostimulation versus sham. *Spine J.* 2026;26(5):996-1005. PMID: 41397571
19. Goree JH, Grant SA, Dickerson DM, et al. Randomized Placebo-Controlled Trial of 60-Day Percutaneous Peripheral Nerve Stimulation Treatment Indicates Relief of Persistent Postoperative Pain, and Improved Function After Knee Replacement. *Neuromodulation : journal of the International Neuromodulation Society.* 2024;27(5):847-61. PMID: 38739062
20. Gilligan C, Volschenk W, Russo M, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. *Pain.* 2021;162(10):2486-98. PMID: 34534176
21. Gilligan C, Volschenk W, Russo M, et al. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial. *Neuromodulation : journal of the International Neuromodulation Society.* 2023;26(1):87-97. PMID: 35088722
22. Gilligan C, Volschenk W, Russo M, et al. Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction. *Neuromodulation : journal of the International Neuromodulation Society.* 2023;26(1):98-108. PMID: 36175320
23. Gilligan C, Volschenk W, Russo M, et al. Five-Year Longitudinal Follow-Up of Restorative Neurostimulation Shows Durability of Effectiveness in Patients With Refractory Chronic Low Back Pain Associated With Multifidus Muscle Dysfunction. *Neuromodulation : journal of the International Neuromodulation Society.* 2024;27(5):930-43. PMID: 38483366
24. Ilfeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study. *Anesthesiology.* 2021;135(1):95-110. PMID: 33856424
25. Gilmore CA, Ilfeld BM, Rosenow JM, et al. Percutaneous 60-day peripheral nerve stimulation implant provides sustained relief of chronic pain following amputation: 12-month follow-up of a randomized, double-blind, placebo-controlled trial. *Reg Anesth Pain Med.* 2019. PMID: 31740443
26. Gilmore C, Ilfeld B, Rosenow J, et al. Percutaneous peripheral nerve stimulation for the treatment of chronic neuropathic postamputation pain: a multicenter, randomized, placebo-controlled trial. *Reg Anesth Pain Med.* 2019;44(6):637-45. PMID: 30954936
27. Wilson RD, Gunzler DD, Bennett ME, et al. Peripheral nerve stimulation compared with usual care for pain relief of hemiplegic shoulder pain: a randomized controlled trial. *Am J Phys Med Rehabil.* 2014;93(1):17-28. PMID: 24355994

28. Deer T, Pope J, Benyamin R, et al. Prospective, Multicenter, Randomized, Double-Blinded, Partial Crossover Study to Assess the Safety and Efficacy of the Novel Neuromodulation System in the Treatment of Patients With Chronic Pain of Peripheral Nerve Origin. *Neuromodulation : journal of the International Neuromodulation Society.* 2016;19(1):91-100. PMID: 26799373
29. Deckers K, De Smedt K, Mitchell B, et al. New Therapy for Refractory Chronic Mechanical Low Back Pain-Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial. *Neuromodulation : journal of the International Neuromodulation Society.* 2018;21(1):48-55. PMID: 29244235
30. Thomson S, Chawla R, Love-Jones S, et al. Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort. *Pain Ther.* 2021;10(2):1451-65. PMID: 34478115
31. Mitchell B, Deckers K, De Smedt K, et al. Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain. *Neuromodulation : journal of the International Neuromodulation Society.* 2021;24(6):1024-32. PMID: 34242440
32. Warner NS, Schaefer KK, Eldrige JS, et al. Peripheral Nerve Stimulation and Clinical Outcomes: A Retrospective Case Series. *Pain Pract.* 2020. PMID: 33222402
33. Chmiela MA, Hendrickson M, Hale J, et al. Direct Peripheral Nerve Stimulation for the Treatment of Complex Regional Pain Syndrome: A 30-Year Review. *Neuromodulation : journal of the International Neuromodulation Society.* 2020. PMID: 33098229
34. Oswald J, Shahi V,Chakravarthy KV. Prospective case series on the use of peripheral nerve stimulation for focal mononeuropathy treatment. *Pain management.* 2019;9(6):551-58. PMID: 31686589
35. Ilfeld BM, Gabriel RA, Saulino MF, et al. Infection Rates of Electrical Leads Used for Percutaneous Neurostimulation of the Peripheral Nervous System. *Pain Pract.* 2017;17(6):753-62. PMID: 27676323
36. Deer TR, Levy RM,Rosenfeld EL. Prospective clinical study of a new implantable peripheral nerve stimulation device to treat chronic pain. *Clin J Pain.* 2010;26(5):359-72. PMID: 20473041
37. Frederico TN,da Silva Freitas T. Peripheral Nerve Stimulation of the Brachial Plexus for Chronic Refractory CRPS Pain of the Upper Limb: Description of a New Technique and Case Series. *Pain Med.* 2020;21(Suppl 1):S18-S26. PMID: 32804227
38. Mansfield JT,Desai MJ. Axillary Peripheral Nerve Stimulation for Chronic Shoulder Pain: A Retrospective Case Series. *Neuromodulation : journal of the International Neuromodulation Society.* 2020;23(6):812-18. PMID: 31930660
39. Gilmore CA, Kapural L, McGee MJ, et al. Percutaneous Peripheral Nerve Stimulation for Chronic Low Back Pain: Prospective Case Series With 1 Year of Sustained Relief Following Short-Term Implant. *Pain Pract.* 2020;20(3):310-20. PMID: 31693791
40. Ardeshiri A, Shaffrey C, Stein KP, et al. Real-World Evidence for Restorative Neurostimulation in Chronic Low Back Pain-a Consecutive Cohort Study. *World Neurosurg.* 2022;168:e253-e59. PMID: 36184040
41. Abd-Elsayed A. Wireless Peripheral Nerve Stimulation for Treatment of Peripheral Neuralgias. *Neuromodulation : journal of the International Neuromodulation Society.* 2020;23(6):827-30. PMID: 32128933
42. Mainkar O, Solla CA, Chen G, et al. Pilot Study in Temporary Peripheral Nerve Stimulation in Oncologic Pain. *Neuromodulation : journal of the International Neuromodulation Society.* 2020;23(6):819-26. PMID: 32185844

43. Bina RW, Palsma RS, Weinand ME, et al. Peripheral Nerve Stimulation for Refractory Trigeminal Pain: Recent Single-Institution Case Series With Long-Term Follow-Up and Review of the Literature. *Neuromodulation : journal of the International Neuromodulation Society.* 2020;23(6):796-804. PMID: 32141164
44. Sarica C, Iorio-Morin C, Aguirre-Padilla DH, et al. Clinical outcomes and complications of peripheral nerve field stimulation in the management of refractory trigeminal pain: a systematic review and meta-analysis. *J Neurosurg.* 2022:1-9. PMID: 35180702
45. Hofmeister M, Memedovich A, Brown S, et al. Effectiveness of Neurostimulation Technologies for the Management of Chronic Pain: A Systematic Review. *Neuromodulation : journal of the International Neuromodulation Society.* 2020;23(2):150-57. PMID: 31310417
46. van Gorp E, Teernstra O, Aukes HJ, et al. Long-Term Effect of Peripheral Nerve Field Stimulation as Add-On Therapy to Spinal Cord Stimulation to Treat Low Back Pain in Failed Back Surgery Syndrome Patients: A 12-Month Follow-Up of a Randomized Controlled Study. *Neuromodulation : journal of the International Neuromodulation Society.* 2019;22(8):970-77. PMID: 29608807
47. Albright-Trainer B, Phan T, Trainer RJ, et al. Peripheral nerve stimulation for the management of acute and subacute post-amputation pain: a randomized, controlled feasibility trial. *Pain management.* 2022;12(3):357-69. PMID: 34761694
48. van Gorp EJ, Teernstra OP, Gultuna I, et al. Subcutaneous Stimulation as ADD-ON Therapy to Spinal Cord Stimulation Is Effective in Treating Low Back Pain in Patients With Failed Back Surgery Syndrome: A Multicenter Randomized Controlled Trial. *Neuromodulation : journal of the International Neuromodulation Society.* 2016;19(2):171-8. PMID: 26890014
49. Eldabe SS, Taylor RS, Goossens S, et al. A Randomized Controlled Trial of Subcutaneous Nerve Stimulation for Back Pain Due to Failed Back Surgery Syndrome: The SubQStim Study. *Neuromodulation : journal of the International Neuromodulation Society.* 2019;22(5):519-28. PMID: 29704437
50. McRoberts WP, Wolkowitz R, Meyer DJ, et al. Peripheral nerve field stimulation for the management of localized chronic intractable back pain: results from a randomized controlled study. *Neuromodulation : journal of the International Neuromodulation Society.* 2013;16(6):565-74; discussion 74-5. PMID: 23577773
51. Kloimstein H, Likar R, Kern M, et al. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. *Neuromodulation : journal of the International Neuromodulation Society.* 2014;17(2):180-7. PMID: 24320718
52. Verrills P, Rose R, Mitchell B, et al. Peripheral nerve field stimulation for chronic headache: 60 cases and long-term follow-up. *Neuromodulation : journal of the International Neuromodulation Society.* 2014;17(1):54-9. PMID: 24165152
53. Verrills P, Vivian D, Mitchell B, et al. Peripheral nerve field stimulation for chronic pain: 100 cases and review of the literature. *Pain Med.* 2011;12(9):1395-405. PMID: 21812906
54. Sator-Katzenschlager S, Fiala K, Kress HG, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. *Pain Pract.* 2010;10(4):279-86. PMID: 20230450
55. Manchikanti L, Sanapati MR, Soin A, et al. Comprehensive Evidence-Based Guidelines for Implantable Peripheral Nerve Stimulation (PNS) in the Management of Chronic Pain: From the American Society Of Interventional Pain Physicians (ASIPP). *Pain Physician.* 2024;27(S9):S115-s91. PMID: 39565237

56. Strand N, D'Souza RS, Hagedorn JM, et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. *J Pain Res.* 2022;15:2483-504. PMID: 36039168
57. Peripheral nerve-field stimulation for chronic low back pain: guidance [IPG451]. Secondary Peripheral nerve-field stimulation for chronic low back pain: guidance [IPG451] [cited 6/25/2026]. 'Available from:' https://www.nice.org.uk/guidance/ipg451.

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

Codes	Number	Description
		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
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

Date of Origin: *January 2018*