# Medical Coverage Policy

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# Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation

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## Overview

This Coverage Policy addresses implantable peripheral nerve stimulation (PNS) and peripheral nerve field stimulation (PNFS) for the treatment of pain conditions.

For the use of electrical stimulation in the treatment of headache, occipital, or trigeminal neuralgia, see Cigna Medical Coverage policy "Headache, Occipital, and/or Trigeminal Neuralgia Treatment".

## Coverage Policy

**Implantable peripheral nerve stimulation (PNS) for the treatment of acute or chronic pain conditions is considered not medically necessary.**

**Implantable peripheral nerve field stimulation (PNFS) is considered experimental, investigational or unproven for any indication.**

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

## General Background

**Peripheral Nerve Stimulation (PNS)**
Implantable peripheral nerve stimulation (PNS) for the treatment of pain conditions involves the implantation of electrodes on or near a peripheral nerve which has been identified as transmitting pain to a specific area of the body. PNS has been proposed for the treatment of chronic pain that is not responsive to conservative treatments. The aim of PNS is to deliver repetitive electrical

stimulation to the nerve that is involved in pain production or transmission; the therapy does not cure underlying pain syndromes (Slavin, 2022). Chronic pain conditions for which PNS has been proposed include: hemiplegic shoulder pain, back pain, carpal tunnel syndrome; causalgia, complex regional pain syndrome, failed back syndrome, fibromyalgia, hemiplegic shoulder pain, brachial plexus injuries, post-trauma pain, subacromial impingement syndrome, post-amputation pain, postherpetic neuralgia, stroke, testicular pain, and trigeminal neuropathy (International Neuromodulation Society [INS], 2019; Reverberi, et al., 2014; Stevanato, et al., 2014; Wilson, et al., 2014; Stidd, et al., 2012). There is insufficient evidence to support the safety and effectiveness of PNS for the treatment of pain conditions.

PNS systems include a neurostimulator (pulse generator), leads (thin wires with electrodes), a controller (remote control device that allows the patient to control the device), and a programmer that is a remote control device that allows a medical professional to make adjustments to the settings of the pulse generator. The leads are positioned and connected to the generator. PNS procedures are usually performed in stages, wherein electrodes are first implanted for trialing purposes prior to permanent implantation of the generator. If the trial is deemed successful (usually defined has >50% response rate in pain reduction), the generator and/or electrodes are permanently implanted in the chest, abdomen or buttocks.

For the use of electrical stimulation in the treatment of headache or occipital neuralgia, see Cigna Medical Coverage policy "Headache, Occipital, and/or Trigeminal Neuralgia Treatment".

For the use of sacral nerve stimulation (SNS), percutaneous tibial nerve stimulation (PTNS), and implantable tibial nerve stimulation for the treatment of fecal incontinence and urinary conditions, see Cigna Medical Coverage policy "Sacral Nerve and Tibial Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation".

**U.S. Food and Drug Administration (FDA):** In recent years, several implantable peripheral nerve stimulators for the treatment of pain conditions have received FDA 510(k) clearance and are classified as Class II devices. The FDA-approved indications for use of these devices include:

- pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach
- not intended to treat pain in the craniofacial region

Examples of FDA-approved implantable peripheral nerve stimulators for pain relief include:

- Freedom® Peripheral Nerve Stimulator (PNS) System (Curonix, Pompano Beach, FL; 2024)
- Moventis PNS (Micron Medical Corporation, Boca Raton, FL; 2020)
- Nalu Neurostimulation System (Nalu Medical, Inc., Carlsbad, CA; 2019)
- Neuspera Neurostimulation System (Neuspera Medical Inc., San Jose, CA, 2021)
- SPRINT PNS System (SPR Therapeutics, Cleveland, OH; 2017) (approved for short term, 60-day treatment only)
- StimRouter Neuromodulation System (Bioness Inc., Valencia, CA; 2015)

The Reactiv8 Implantable Neurostimulation System (Mainstay Medical, Brooklyn Center, MN) received FDA premarket (PMA) approval in June 2020. The FDA approval order stated the device is indicated for "bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3 as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy including pain medications and physical therapy and are not candidates for spine surgery." Potential complications associated with the use of the ReActiv8

System include lead or implanted pulse generator (IPG) migration; skin erosion; persistent pain at lead or IPG sites; nerve or muscular damage; loss of pain relief over time; and ineffective pain control due to system component or battery issues.

**Literature Review:** There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of implanted peripheral nerve stimulation for the treatment of acute or chronic pain conditions. Some prospective and randomized controlled studies have been completed, however evidence is primarily in the form of case reports, retrospective reviews, and case series with small patient populations, short duration of follow-up, and lack of a sham or untreated control group (Goree, et al., 2024; Abd-Elsayed and Moghim, 2023; Ardeshiri, et al., 2022; Deer, et al., 2021; Gilligan, et al., 2021a; Cohen, et al., 2019; Gilmore, et al., 2019a; Gilmore, et al., 2019c; Ilfeld, et al., 2019; Oswald, et al., 2019; Deckers, et al., 2018; Gilmore, et al., 2018; Wilson et al., 2017; Deer, et al., 2016; Reverberi, et al., 2014; Stevanato, et al., 2014; Wilson, et al., 2014; Stidd, et al., 2012).

Systematic reviews evaluating implanted PNS for the treatment of various pain conditions have been published in the literature. Most include prospective and retrospective studies of varying size, with wide variations in patient populations, interventions, and study design. Authors consistently note a lack of high-quality RCTs, and heterogeneity among the studies which precludes meta-analysis (Xu, et al., 2022; Chou, et al., 2021; Deer, et al., 2020). There remains poor understanding of the underlying mechanisms of PNS, appropriate patient selection, or long-term outcomes of therapy.

Schwab et al. (2025) reported on the first year outcomes of the RESTORE trial, a multicenter, open label randomized controlled trial which compared outcomes in individuals with chronic low back pain (CLBP) associated with multifidus dysfunction treated with restorative neurostimulation (Reactiv8) along with optimal medical management (OMM), versus a control group receiving OMM alone. All subjects received OMM, which included medications; non-pharmacological, physical, or psychosocial therapies; and more invasive interventions such as blocks and injections. Subjects randomized to the treatment group were also treated with ReActiv8. Subjects were instructed to initiate therapy daily over at least two sessions, for a maximum of 60 minutes per day. The study inclusion criteria were age over 21; lumbar multifidus muscle dysfunction; intractable CLBP rated 6-9 persisting over six months; failure of therapy; not a candidate for spinal surgery; Oswestry Disability Index (ODI) score $\geq 30$ and $\leq 60$; and on OMM. Exclusion criteria included a contraindication for the ReActiv8 system; BMI $> 35$; prior surgical correction for scoliosis or current moderate to severe scoliosis; known/suspected cause of CLBP amenable to surgery; worse leg pain than back pain; radiculopathy below the knee; previous back surgery at or below T8; previous thoracic or lumbar sympathectomy; lumbar medial branch rhizotomies within prior year; lumbar medial branch blocks within prior 30 days; past or current neuromodulation devices; pregnant or planning to be pregnant in the next year; muscle wasting, muscle atrophy, or progressive neurological disease; active disruptive psychological or psychiatric disorder; opioid addiction or drug-seeking behavior; active malignancy; active infection; poorly controlled diabetes; current smoking; condition requiring MRI or diathermy; life expectancy less than one year; and pending or approved financial compensation claim. The authors stated a minimum of 204 evaluable patients was needed to sufficiently power the primary endpoint. A total of 226 subjects were randomized; 23 subjects withdrew prior to follow up; 203 were included in the modified intention-to-treat analysis; and 188 (83%) subjects completed the one year follow up. There was a statistically significant difference between the treatment and control groups in Depression Anxiety and Stress Scale (DASS) ($5.3 \pm 5.6$ vs $7.1 \pm 6.2$, respectively; $p=0.040$), and active depression (38% vs 62%, respectively; $p=0.029$). The primary outcome measure was mean change in the Oswestry Disability Index (ODI). Secondary outcome measures included change from baseline in average low back pain in the prior 24 hours, and change from baseline in quality of life using the EuroQol Five-Dimension Scale (EQ-5D-5L). At one year, the mean change

in ODI between the treatment and control groups was statistically significant (−19.7 ± 1.4 vs −2.9 ± 1.4; between-group difference of 16.8 ± 1.9; 95% confidence interval [CI] [− 20.6 to − 13.0 points]; p<0.001). Secondary outcome measures were statistically significant in the treatment group versus the control group, for change in back pain (−3.6 ± 0.2 vs −0.6 ± 0.2; between-group difference of −3.0 ± 0.3; 95% CI [−3.6, −2.5]; p<0.001) and change in healthcare-related EQ-5D-5L (0.155 ± 0.012 vs 0.008 ± 0.012; between-group difference of 0.147 ± 0.018; 95% CI [0.112, 0.1821]; p<0.001). There were 31 device-, procedure-, and/or therapy-related adverse events in 23 treatment group subjects. These included implant site pocket pain and infection; device overstimulation; lead fracture; implant site seroma and dermatitis; anesthetic complications; delayed healing; aggravated back pain; radicular pain; shoulder pain; syncope; and wound infection. Eight Reactiv8 system modifications were performed in seven patients, and included explants; lead revisions; and implantable pulse generator pocket revision. Limitations of the study included the lack of participant blinding to treatment; loss to follow up; treatment adherence/compliance was not addressed; study was potentially underpowered; and race/ethnicity of the participants was not addressed. These are the reported one-year outcomes; subjects will be followed for an additional year. The study was funded by Mainstay Medical, Inc.

Hatheway et al. (2024a and 2024b) conducted a randomized controlled trial (n=89) to evaluate peripheral nerve stimulation (PNS) with a micro-implantable pulse generator (micro-IPG; Nalu Neurostimulation System) for the treatment of chronic peripheral pain. Fifty-eight subjects were randomized to the Nalu treatment group, and 31 to the control group. Those in the Nalu group received PNS and conventional medical management (CMM) throughout the trial. Subjects in the control group received CMM alone for three months, at which time 24 subjects crossed over to the Nalu group. The inclusion criteria were age 18-80; chronic, intractable post-surgical/post-traumatic peripheral pain/neuralgia, mononeuropathy, other neuralgia or neuropathic pain, or osteoarthritic pain, affecting of the lower back, shoulder, knee or foot/ankle; pain score of at least six and exclusive of the craniofacial region; and currently on CMM stable pain medication use/dosage for 30 days. Exclusion criteria included an active implantable medical device; previously failed PNS, spinal cord stimulation, or dorsal root ganglion therapy; pain absent at rest; complex regional pain syndrome, peripheral neuralgia of metabolic origin, post-herpetic neuralgia, metabolic or genetic neuropathy; successful interventional procedure within prior three months to treat the same pain condition(s); uncontrolled depression or psychiatric disorders; pending/ongoing legal issues or conflicting secondary gain issues related to chronic pain condition; coagulation disorder, bleeding diathesis, or progressive peripheral vascular disease; active systemic infection; active malignancy or paraneoplastic syndrome; uncontrolled diabetes; alcohol or drug dependency within prior six months; pregnancy; nursing/breastfeeding; on ≥90 mg-morphine equivalents per 24 hours; and prior ablative treatments. The primary outcome measure was the numeric rating scale (NRS) pain score from the target area of peripheral pain. Secondary outcome measures included the Patient Global Impression of Change (PGIC), Brief Pain Inventory Short Form (BPI-SF), quality-of-life metric (EuroQoL [EQ-5D-5L]), Beck Depression Inventory (BDI) and Oswestry Disability Index (ODI). Follow ups were completed at three, six, and twelve months. Sixty one subjects (69%) completed the 12-month follow up. A modified-intention-to-treat analysis was performed. At three and six months, subjects in the Nalu group achieved a 67% and 70% improvement in pain, respectively, compared with baseline (p<0.001). The control group achieved a 6% improvement in pain at three months. At 12 months, the responder rate was 87% (53/61) with an average pain reduction of 69%. Mean pain scores (NRS) improved from 7.5 ± 1.20 at baseline to 2.3 ± 1.7 at 12 months. For PGIC, 48% (29/61) reported very much improved, 44% (27/61) reported much improved, 3% (2/61) reported minimally improved, and 5% (3/61) reported no change. At 12 months, 93% (57/61) of subjects reported continued use of oral medications and 20% (12/61) using topical applications for pain. Adverse events included generator migrations, lead migrations, lead fractures, infections, and wound complications. Revisions and explanations/device discontinuation were needed in some cases. Limitations of the

study included lack of participant blinding, heterogeneity of CMM protocols, 31% drop out rate/loss to follow up, race/ethnicity data was not reported, and device usage/compliance was not addressed. The study was sponsored by Nalu Medical.

Gilligan et al. (2021a) reported on a randomized, double-blind, sham-controlled trial to determine safety and efficacy of an implantable, restorative neurostimulator (ReActiv8), designed to restore control of the multifidus muscle and facilitate relief of symptoms, namely low back pain (LBP). The study included 204 patients with refractory mechanical (musculoskeletal) chronic LBP and a positive prone instability test indicating impaired multifidus control. Subjects were implanted and randomized to therapeutic (n=102) or low-level sham (n=102) stimulation of the medial branch of the dorsal ramus nerve (multifidus nerve supply) for 30 minutes twice daily. The primary endpoint was the comparison of responder proportions (≥ 30% relief on the LBP visual analogue scale without analgesics increase) at 120 days. After the primary endpoint assessment, participants in the sham-control group switched to therapeutic stimulation and the combined cohort was assessed through one year for long-term outcomes and adverse events. There was no comparative assessment at one year. The primary endpoint was inconclusive in terms of treatment superiority (57.1% vs 46.6%; difference: 10.4%; 95% confidence interval, −3.3% to 24.1%, p=0.138). Eight device- or procedure-related serious adverse events were reported in eight participants (4%), all before the 120-day follow-up. At the time of publication, participant follow-up was intended for a total of five years, to provide additional insights into the long-term benefits, risks, and reliability of the device.

Gilligan et al. (2021b) reported on the two-year outcomes of the ReActiv8 neurostimulator in patients with disabling chronic low back pain (CLBP) secondary to multifidus muscle dysfunction, and no indications for spine surgery (follow-up of above the Gilligan, et al., 2021a trial). Open-label follow-up of 204 participants implanted with the ReActiv8 restorative neurostimulation system was performed. Pain intensity (visual analog scale [VAS] in centimeters [cm]), disability (Oswestry disability index [ODI]), quality-of-life (EQ-5D-5L), and opioid intake were assessed at baseline, six months, one year, and two years after activation. A total of 156 participants (76%) were included in the two-year analysis. The proportion of participants with ≥ 50% CLBP relief was 71%, and 65% reported CLBP resolution (VAS ≤ 2.5 cm); 61% had a reduction in ODI of ≥ 20 points, 76% had improvements of ≥ 50% in VAS and/or ≥ 20 points in ODI, and 56% had these substantial improvements in both VAS and ODI. A total of 87% of participants had continued device use during the second year for a median of 43% of the maximum duration, and 60% (34 of 57) had voluntarily discontinued (39%) or reduced (21%) opioid intake. Over the preceding two years, 45 participants (22%) had undergone a total of 47 surgical interventions, during which 32 systems were removed. Reasons for system removal included a lack of efficacy (n=18), infection (n=6), as a safety precaution before MRI (n=6), resolution of LBP (n=1), and relocation to a remote area without device follow-up infrastructure (n=1).

Gilligan et al. (2023) completed a three-year outcomes analysis of the above Reactiv8 trial (Gilligan, et al., 2021a), which included data on 133 participants (65% of the original cohort). Between the two- and three-year follow-up analyses, 17 patients withdrew for various reasons: seven had the Reactiv8 device explanted for inadequate response; six explanted for pain resolution; two were lost to follow-up; one explanted for MRI; and there was one unrelated death. By three years, the mean average low back pain (LBP) visual analog scale (VAS) score had improved by −4.9 ± 0.2 cm (95% confidence interval [CI], −5.3 to −4.5; p<0.0001), and 100/130 (77%) of participants had a ≥ 50% reduction in VAS; 80/130 (62%) of participants had a ≥ 70% VAS reduction, and 87/130 (67%) had resolution of chronic low back pain (CLBP) (VAS ≤ 2.5 cm). The mean Oswestry Disability Index (ODI) score improved by −22.7 ± 1.3 (95% CI, −25.3 to −20.1; p<0.0001), and 82/131 (63%) of participants had a ≥ 20 point ODI reduction. The proportion of participants with a reduction in LBP VAS of ≥ 50% and/or ODI of ≥ 20-points without an increase in either was 109/131 (83%). The proportion who exceeded these

cut-offs in both VAS and ODI was 73/130 (56%). Of the participants with three-year follow-up data, 51/133 (38%) were taking opioids at baseline, and 36/51 (71%) had voluntarily discontinued (25/51 [49%]) or reduced (11/51 [22%]) opioid dosage. Over the three-year follow-up period, 25 devices were removed for inadequate response to Reactiv8 therapy, and seven were removed due to resolution of low back pain. No additional device or procedure-related serious adverse events were reported.

Gilligan et al. (2024) published the five-year outcomes of the above Reactiv8 trial (Gilligan, et al., 2021a), which included data on 126 participants (62% of the original cohort). At the five-year follow up, the mean average low back pain had improved from 7.3 ± 0.2 cm at baseline to 2.4 ± 0.2 cm (−67.5% ± 3.1% [95% confidence interval [CI] −73.5 to −61.5]; p<0.0001); 89 of 124 participants (71.8%) had a reduction in visual analog scale (VAS) of ≥ 50%, and 83 of 124 (66.9%) had resolution of chronic low back pain (VAS of ≤ 2.5 cm). The mean Oswestry Disability Index (ODI) improved from 39.1 ± 10.3 points at baseline to 16.5 ± 1.3 (−22.7 ± 1.4 [95% CI −25.4 to −20.8]; p<0.0001), and 77 of 126 participants (61.1%) had an ODI reduction of ≥ 20. The mean EuroQol EQ-5D-5L index improved by 0.231 ± 0.018 (95% CI 0.195–0.267; p<0.0001). Of the 52 subjects who were on an opioid-containing medication at baseline and had a five-year visit, 69% either discontinued (46%) or decreased (23%) intake. Over the five-year study, a total of 27 (13%) of participants had the device removed for inadequate pain response, while 18 participants (9%) had the device removed for resolution of low back pain (with a mean residual VAS of 2.3 ± 0.5 cm and ODI of 9.6 ± 2.2). Author-noted limitations included that the sham-control group was not maintained during long-term follow up, and direct correlations with objective device usage and multifidus structure/function were not made. The study was funded by Mainstay Medical, Inc.

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

Gilmore et al. (2019c) conducted a double-blinded, randomized, placebo-controlled study with 28 lower extremity amputees with postamputation neuropathic pain. The subjects underwent ultrasound-guided implantation of percutaneous PNS leads and were randomized to receive either peripheral nerve stimulation (PNS) with the SPRINT pulse generator (SPR Therapeutics), or placebo (sham stimulation) for four weeks. The placebo group then crossed over and all subjects received PNS for four additional weeks. The primary efficacy endpoint evaluated the proportion of

subjects reporting ≥ 50% pain reduction during one to four weeks. A greater proportion of subjects receiving PNS (n=7/12, 58%, p=0.037) demonstrated ≥ 50% reductions in average postamputation pain during weeks one through four, compared with subjects receiving placebo (n=2/14, 14%). Two subjects were excluded from efficacy analysis due to eligibility changes. Greater proportions of PNS subjects also reported ≥ 50% reductions in pain (n=8/12, 67%, p=0.014) and pain interference (n=8/10, 80%, p=0.003) after eight weeks of therapy compared with subjects receiving placebo (pain: n=2/14, 14%; pain interference: n=2/13, 15%). Author-noted limitations of the study included the small number of subjects; partial crossover design; variation in lead replacement in the placebo group at time of crossover; and high variation in opioid use.

Gilmore et al. (2019b) reported on 12-month outcomes in the cohort in the above study (Gilmore, et al., 2019c). Nine participants from the PNS group (64% of the initial 14 participants) and six from the placebo group (43% of the original group of 14) were assessed at 12 months. It was noted that more participants in the PNS group reported ≥ 50% reductions in average weekly pain at 12 months (67%, 6 of 9 subjects) compared with the placebo at the end of the placebo period (0%, 0/14, p=0.001). In addition, 56% (5 of 9) participants in the PNS group reported ≥50% reductions in pain interference at 12 months, compared with 2/13 (15%, p=0.074) in the original placebo group at crossover. Limitations of the study included the small number of subjects and considerable loss to follow up (46%).

Deckers et al. (2018) conducted a prospective single arm trial to evaluate restorative neurostimulation of the lumbar multifidus using the ReActiv8 device, for the treatment of chronic mechanical low back pain (CMLBP) in patients who failed conventional therapy and were not candidates for surgery or spinal cord stimulation (SCS). The study included fifty-three patients who were implanted with the ReActiv8 neurostimulator. Leads were positioned bilaterally with electrodes close to the medial branch of the L2 dorsal ramus nerve. The primary outcome measure was low back pain evaluated on a 10-Point Numerical Rating Scale (NRS). Responders were defined as subjects with an improvement of at least the Minimal Clinically Important Difference (MCID) of ≥ 2-points in low back pain NRS without a clinically meaningful increase in LBP medications at 90 days. Secondary outcome measures included Oswestry Disability Index (ODI) and Quality of Life (QoL; EQ-5D). For 53 subjects with an average duration of CLBP of 14 years and average NRS of 7 and for whom no other therapies had provided satisfactory pain relief, the responder rate was 58%. The percentage of subjects at 90 days, six months, and one year with ≥ MCID improvement in single day NRS was 63%, 61%, and 57%, respectively. Percentage of subjects with ≥ MCID improvement in ODI was 52%, 57%, and 60% while those with ≥ MCID improvement in EQ-5D was 88%, 82%, and 81%. There were no unanticipated or serious adverse events related to the device, procedure, or therapy. The initial surgical approach led to a risk of lead fracture, which was mitigated by a modification to the surgical approach. Potential limitations of the study included the small number of patients, lack of randomization, and lack of a control group.

Mitchell et al. (2021) reported on the four-year results of the above study (Deckers, et al., 2018); data was available on 33 patients (62% of the original cohort). Subjects reported mean scores (± standard error of the mean): low back pain Numeric Rating Scale (NRS) of 3.2 ± 0.4; Oswestry Disability Index (ODI) score of 23.0 ± 3.2; and European Quality of Life Score on Five Dimensions (EQ-5D) score of 0.721 ± 0.035; indicating mean improvements from baseline were statistically significant (p<0.001). Seventy three percent of participants had a clinically meaningful improvement of ≥ 2 points on NRS; 76% of ≥ 10 points on ODI; and 62.5% had a clinically meaningful improvement in both NRS and ODI. The authors noted the high dropout rate and relatively high lead revision rate may have impacted reported outcomes.

Deer et al. (2016) conducted a prospective, multicenter, randomized, double-blind, partial crossover study to assess the safety and efficacy of the StimRouter System for the treatment of severe, intractable peripheral nerve pain associated with posttraumatic or postsurgical neuralgia. Ninety-four patients were randomized to the treatment group (n=45) or the control group (n=49). Primary outcomes included pain relief (measured by average pain at rest using a numerical rating scale [NRS]) over three months' time; and safety, (determined by assessment of adverse events [AEs]) during the one-year study period. The treatment group received electrical stimulation from the StimRouter System and stable dosing of pain medications, while the control group received no therapeutic stimulation and a stable dose of pain medications. At three months, patients in the treatment group achieved a higher response rate of 38% vs. the 10% rate found in the control group ($p=0.0048$). The treatment group achieved a mean pain reduction of 27.2% from baseline to month three, compared to a 2.3% reduction in the control group ($p<0.0001$). There were no serious adverse events related to the device. For safety follow-up, 15 did not participate in the six- and 12-month follow-up and 33 patients at 12 month follow-up, representing an attrition of 51%.

**Peripheral Nerve Field Stimulation (PNFS)**
Peripheral nerve field stimulation (PNFS), also known as subcutaneous peripheral field stimulation, subcutaneous nerve stimulation, or subcutaneous target stimulation (STS), has been proposed for the treatment of chronic cervical, thoracic, or lumbar pain. Electrode leads are placed in subcutaneous tissue around the painful area, and electrical current is applied to create stimulation in the area, or "field" of pain. This technique is different from peripheral nerve stimulation (PNS), in which specific, visible, and identifiable peripheral nerves are targeted. In peripheral nerve field stimulation, many smaller unnamed, nonspecific nerves are targeted. The electrodes are placed in the skin either through an open or percutaneous approach. Imaging guidance is included, when performed. The electrode is placed subcutaneously at the site of maximum pain rather than at the site of the nerve. This technique involves a temporary trial period for approximately two to 14 days. A trial may be considered "successful" if there is at least a 50% reduction in pain. Following a successful temporary trial, the device is implanted. The most common complications associated with PNFS include lead migration, skin erosion, and infection (Barolat, 2018). The role of PNFS in the management of pain conditions has not been established.

**Literature Review:** Comparative controlled trial data evaluating PNFS in the published, peer-reviewed scientific literature are limited, and there is currently insufficient evidence to determine safety and effectiveness of this treatment. Evidence is primarily in the form of case series, retrospective reviews, and studies with small patient populations (Eldabe, et al., 2019; Ishak, et al., 2018; Mitchell, et al., 2016; Petersen, et al., 2014; McRoberts, et al., 2013; Verrills, et al., 2011).

Eldabe et al. (2019) conducted the SubQStim randomized controlled trial (RCT) (n=116) to compare the effectiveness of peripheral nerve field stimulation/subcutaneous nerve stimulation (SQS) plus optimized medical management (OMM), versus OMM alone in individuals with back pain due to failed back surgery syndrome (FBSS). Subjects in the SQS+OMM group (n=56) underwent a trial period with subcutaneous lead placement in the area of pain, connected to an external neurostimulator. A successful trial was defined as back pain reduction of > 30% as measured by visual analog scale (VAS), as some reduction in pain along with improved function or quality of life, or as a reduction in pain medication use. Subjects could titrate stimulation as necessary for pain relief. OMM for each subject was defined by the investigator, and varied by type, frequency, duration, and/or dose. Forty five subjects had leads permanently implanted. The control group (n=60) received OMM only. Included in the study were adults with FBSS (i.e., persistent pain for six months following most recent back surgery, no further therapeutic surgical options, and intractable back pain). Excluded from the study were individuals with prior or current implantable neurostimulation or intrathecal drug delivery system; active disruptive psychiatric

disorder; any severe pain condition unrelated to FBSS; spinal fusion > three vertebral levels; or history of coagulation disorder or lupus erythematous. The primary outcome was responder rate (defined as ≥ 50% reduction in back pain intensity from baseline) at nine months. Secondary outcome measures included pain intensity, functional disability using the Oswestry Disability Index (ODI), quality of life, healthcare utilization, pain medication use, and safety (at 36 months). The study was terminated early by the sponsor; 74 subjects completed the nine-month primary endpoint visit. At nine months, the responder rate in the SQS+OMM arm was 33.9% (n=19; 95% confidence interval [CI] [21.5–46.3%]) compared to 1.7% (n=1; 95% CI [0.0–4.9%]) in the OMM group (p<0.0001). There were 193 events reported up to the 36-month visit (103 in SQS+OMM, 90 in OMM); 15 were device-related. Limitations of the study included lack of blinding; variation in lead type and placement, device programming parameters, and degree of stimulation; variation in OMM treatment; missing data; and subjects had already failed OMM upon enrollment, thus a significant improvement in the OMM group was unlikely.

Ishak et al. (2018) conducted a study to assess the usefulness, safety and efficacy of subcutaneous peripheral nerve field stimulation (SPNS) in patients with chronic low back pain (CLBP). Twenty-six consecutive patients with CLBP were prospectively enrolled in the study. Two electrodes were implanted vertically at a depth of one cm into the subcutaneous tissue, ≤ 10 cm from the region of maximum pain. Trial neurostimulation was performed in all patients for 14 days. A successful outcome was defined as at least 50% pain relief. To evaluate the effects of permanent neurostimulation, the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI), and quality of life (EQ-5D-3L) were scored preoperatively and at six-month and 24-month follow-ups. Thirteen patients responded to trial stimulation and had a permanent neurostimulator implanted. The use of pain medication, including opioid analgesics, was reduced in 92% of patients after 24 months. VAS, ODI, and EQ-5D-3L scores were improved in these patients at the 24-month follow-up. The complication rate was 23% (3/13 patients). In non-responders, the VAS and ODI at 24 months dropped as well but the decrease was less pronounced compared to responders and did not lead to decrease in pain medication. The study was limited by small number of participants and lack of randomization. Large prospective, randomized, controlled studies are needed to confirm findings.

**Professional Societies/Organizations**
**American Society of Interventional Pain Physicians (ASIPP):** In 2024, ASIPP published guidelines for the use of implantable peripheral nerve stimulation (PNS) for the management of chronic pain. The consensus statements were based on a literature review which included seven systematic reviews, eight randomized controlled trials, and nine observational studies covering all PNS treatments. The level of evidence for recommendations related to direct PNS interventions ranged from "Low" to "Fair", and the strength of those recommendations was rated as "Moderate". The recommendations included the following (Manchikanti, et al., 2024):

1. "There is evidence supporting the accuracy and value of diagnostic methods for diagnosing conditions amenable to peripheral nerve stimulation. Evidence Level: Low; Strength of Recommendation: Moderate
2. The evidence of effectiveness of peripheral nerve stimulation in managing chronic pain, based on evidence synthesis utilizing comprehensive and systematic review of the literature with methodologic quality assessment of all studies, applying GRADE criteria, and best evidence synthesis for implantable peripheral nerve stimulation systems following a trial or selective lumbar medial branch stimulation without a trial, is Level III or fair with moderate certainty utilizing GRADE criteria. Evidence Level: Fair; Strength of Recommendation: Moderate
3. The evidence of effectiveness of peripheral nerve stimulation in managing chronic pain based on evidence synthesis utilizing comprehensive and systematic review of the literature with methodologic quality assessment of all studies, applying GRADE criteria, and

best evidence synthesis for implantable stimulation systems following temporary peripheral nerve stimulation for 60 days is Level III or fair with moderate certainty utilizing GRADE criteria. Evidence Level: Fair; Strength of Recommendation: Moderate

4. Based on the evidence and the recommendations, indications may be expanded from present CMS guidance with addition of craniofacial pain, phantom limb pain, and low back pain, either nociceptive or neuropathic, with present evidence showing Level III or fair with moderate certainty utilizing GRADE criteria. Evidence Level: Fair; Strength of Recommendation: Moderate
5. It is important to understand each type of peripheral nerve stimulation implant with features of the equipment and technical requirements. Evidence Level: Moderate; Strength of Recommendation: Strong
6. Based on the available evidence and all the available guidance, patient education is a crucial aspect of success of peripheral nerve stimulation. Evidence Level: Moderate; Strength of Recommendation: Strong
7. Risk stratification of peripheral nerve stimulation, based on ASIPP guidelines: low risk for peripheral nerve stimulation trial and implantation of extremities and other superficial nerves, moderate risk for lumbar medial branches and high risk for thoracic and cervical medial branches, trigeminal and cranial nerve blocks and nerve stimulation. Evidence Level: Moderate; Strength of Recommendation: Moderate
8. Antiplatelet and anticoagulant therapy guidelines in continuation, discontinuation, and re-establishment are utilized as per ASIPP guidelines for low- and high-risk procedures. Evidence Level: Moderate; Strength of Recommendation: Moderate"

**American Society of Pain and Neuroscience (ASPN):** In 2022, ASPN published guidelines on the use of implantable peripheral nerve stimulation (PNS) for the treatment of chronic pain. The investigating panel conducted a systematic review which included 20 randomized controlled trials (RCTs) and 33 prospective observational studies. The studies were heterogeneous in terms of pain conditions treated, including head and neck pain, peripheral neuropathies, back pain, post-amputation pain, among other conditions. The panel then appraised the evidence, developed recommendations, and stratified them by evidence level and degree of recommendation, as such:

| **Level of evidence and study hierarchy by design type** | |
|---|---|
| I | At least one RCT, properly designed |
| II-1 | Well-designed, controlled, non-RCTs |
| II-2 | Cohort or case studies and well-designed controls, multicenter preferable |
| II-3 | Multiple series compared over time, with or without intervention, and surprising results in non-controlled experiences |
| III | Clinical experience-based opinions, descriptive studies, clinical observations, or reports of expert committee |
| **Degree of recommendation** | |
| A | Extremely recommendable (good evidence that the measure if effective and that benefits outweigh the harms) |
| B | Recommendable (at least moderate evidence that the measure if effective and that benefits exceed harms) |
| C | Neither recommendable nor inadvisable (at least moderate evidence that the measure is effective, but benefits are similar to harms and a general recommendation cannot be justified) |

| Level of evidence and study hierarchy by design type | |
|---|---|
| D | Inadvisable (at least moderate evidence that the measure is ineffective or that the harms exceed the benefits) |
| I | Insufficient, low-quality, or contradictory evidence; the balance between benefit and harms cannot be determined |

Having applied the above grading system, ASPN presented the following best practices guidelines:

| Guidelines | Level of Evidence | Grade |
|---|---|---|
| • "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.<br>• PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain.<br>• Subcutaneous peripheral field stimulation and optimal medication management may offer moderate improvement in pain intensity for failed back surgery compared to optimal medication management alone.<br>• PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief.<br>• PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief. | I | B |
| • 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.<br>• There is evidence that PNS of lumbar medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain. | II-2 | B |
| • There is insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain. | II-3 | C |
| • There is limited evidence that PNS may alleviate pain in neuropathic pain syndrome involving the trunk and back including radiculopathy and post-herpetic neuralgia. | III | C |

| Guidelines | Level of Evidence | Grade |
|---|---|---|
| • As a less-invasive modality compared to SCS therapy, PNS may be offered to patients with CRPS Type I or Type II, 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 for CRPS. | | |
| • PNS carries a low-to-intermediate risk for bleeding complications and depends on the proximity of the targeted nerve to critical vessels and invasiveness of PNS implantation." | III | I |

The authors noted PNS neuromodulation is a novel and emerging technology, and RCTs and/or large prospective observational trials are limited (Strand, et al., 2022).

**International Society for the Advancement of Spine Surgery (ISASS):** In a 2023 statement, ISASS stated restorative neurostimulation should be considered for clinically appropriate patients with chronic mechanical low back pain who have exhausted reasonable conservative approaches. ISASS noted that a limited number of studies was available for review, and that industry funding is a potential source of bias (Lorio, et al., 2023).

**National Institute for Health and Care Excellence (NICE):** In 2022, NICE published guidance on the use of neurostimulation of the lumbar muscles to treat refractory non-specific low back pain (e.g., the Reactiv8 device). NICE indicated that the evidence on the safety and efficacy of neurostimulation for this purpose is limited in quantity and quality, and the procedure should only be used "with special arrangements for clinical governance, consent, and audit or research."

## Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| NCD | National | Electrical Nerve Stimulators (160.7) | 8/7/1995 |
| LCD | National | Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) | 6/19/2006 |
| LCD | Noridian Healthcare Solutions, LLC | Peripheral Nerve Stimulation (L34328; L37360) | 12/1/2019 |

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Not Medically Necessary for the treatment of acute or chronic pain conditions:**

| CPT®* Codes | Description |
|---|---|
| 64555 | Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve) |
| 64575 | Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve) |
| 64590 | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling |
| 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) |
| 64999† | Unlisted procedure, nervous system |

†**Note: Considered Experimental, Investigational or Unproven when used to report implantable peripheral nerve field stimulation (PNFS).**

| HCPCS Codes | Description |
|---|---|
| C1767† | Generator, neurostimulator (implantable), non-rechargeable |
| C1778† | Lead, neurostimulator (implantable) |
| C1787† | Patient programmer, neurostimulator |
| C1816† | Receiver and/or transmitter, neurostimulator (implantable) |
| C1820† | Generator, neurostimulator (implantable), with rechargeable battery and charging system |
| C1822† | Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system |
| C1883† | Adaptor/extension, pacing lead or neurostimulator lead (implantable) |
| C1897† | Lead, neurostimulator test kit (implantable) |
| C9807† | Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, nonopioid medical device (must be a qualifying Medicare nonopioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023) |
| L8679† | Implantable neurostimulator, pulse generator, any type |
| L8680† | Implantable neurostimulator electrode, each |
| L8681† | Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only |
| L8682† | Implantable neurostimulator radiofrequency receiver |
| L8683† | Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver |
| L8685† | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |
| L8686† | Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension |

| HCPCS Codes | Description |
|---|---|
| L8687† | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension |
| L8688† | Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension |
| L8689† | External recharging system for battery (internal) for use with implantable neurostimulator, replacement only |
| L8695† | External recharging system for battery (external) for use with implantable neurostimulator, replacement only |

†**Note: Considered Experimental, Investigational or Unproven when submitted with implantable peripheral nerve field stimulation (PNFS).**

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

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## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Annual Review | • No clinical policy statement changes. | 5/15/2025 |
| Annual Review | • Revised policy statement for peripheral nerve stimulation. | 3/15/2024 |