Molina Clinical Policy
Implantable Peripheral Nerve and Nerve Field Stimulators for Chronic Pain
Policy No. 444

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OVERVIEW

Chronic Pain is defined as pain lasting 3 or more months and can result from a myriad of underlying health conditions, such as injury, inflammation, post-surgical complications, various medical conditions, and unknown etiology. According to a 2020 National Center for Health Statistics Data commissioned by the Center for Disease Control, approximately 20% of adults live with chronic pain and approximately 8% of those affected report it interferes with their activities of daily living (Zelaya et al. 2020). The prevalence of chronic pain makes it one of the most common reasons adults seek medical care, incurring significant resources and cost burdens to the healthcare system. Effective chronic pain treatment can be elusive which often leads to increased comorbidities such as mental health and opioid addiction issues, contributing to chronic pain's high healthcare cost. Treatment modalities include, but are not limited to, opioid and non-opioid pharmaceuticals, physical therapy, acupuncture, cognitive behavioral therapy for pain coping mechanisms, nerve blocks, and more.

Implantable Peripheral Nerve Stimulators (PNS) operate on the foundation of the Gate Control Theory of Pain and involve the percutaneous implantation of electrodes on or around specific peripheral nerves that have been identified as contributive to the patient's pain sensation. This modality has been proposed to treat post operative pain, chronic pain of the lower back/knee/shoulder, post-amputation pain, pelvic pain, and complex regional pain syndrome. Predominately performed as a surgical outpatient procedure, peripheral nerve stimulators are semi-permanent electrodes percutaneously implanted and connect to an external pulse generator that is provider programmable and patient controlled.

Implantable peripheral nerve field stimulators (PNFS) differ from PNS in that they are subcutaneously inserted without surgical intervention, and work by creating overlapping stimuli fields to cover a region of smaller nonspecific nerves to induce paresthesia, which theoretically alters a patient's perception of pain. Due to its insertion method, it is also referred to subcutaneous nerve stimulation; however, for the sake of clarity in this policy, it will be referred to peripheral nerve field stimulation. PNFS is often used as an adjunctive therapy to spinal cord stimulation.

Regulatory Status

There are several FDA approved via the 510(k) Premarket Approval Database under the code GZF (stimulator, peripheral nerve, implanted (pain relief) implantable semi-permanent peripheral nerve stimulators on the market. These systems are intended to manage pain and are indicated for adults with severe intractable chronic pain of peripheral nerve origin. The systems are not intended to treat pain in the craniofacial region. Examples of FDA approved peripheral nerve stimulator systems include: StimQ Peripheral Nerve Stimulator (PNS) System (StimQ LLC, Fort Lauderdale, FL); Neuspera Neurostimulation System (NNS) (Neuspera Medical Inc., San Jose, CA); Renew Neurostimulation System (Advanced Neurostimulation Systems, Plano, TX); StimRouter Neuromodulation System (Bioness Inc., Valencia, CA); Nalu Neurostimulation System (Nalu Medical Inc. Carlsbad, CA); Medtronic Peripheral Nerve Stimulation System for Pain Relief [Medtronic X-trel, Mattrix Neurostimulation] (Medtronic Vascular, Minneapolis, MN); and the Moventis PNS System (Micron Medical Corporation, Boca Raton, FL). The SPRINT PNS System (SPR Therapeutics Inc, Cleveland, OH) is FDA approved under the product code NHI, for the same indications as above but only for up to 60 days of therapy.

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There are currently no FDA approved devices specifically for peripheral nerve field stimulation. PNFS can be administered utilizing devices intended for spinal cord stimulation as an off-label use.

The Medtronic System, Nalu Neurostimulation System, Renew Neurostimulation System, and Moventis System are also FDA approved as spinal cord stimulators for pain relief under the product code GZB. While these systems are made by the same companies for the indication of pain, when used in this capacity the systems are implanted directly into the spinal column to induce central nervous system stimulation to treat chronic pain. Spinal cord stimulation is not addressed in this policy.

RELATED POLICIES

MCP-383: IB-Stim Device for Abdominal Pain in Adolescents

COVERAGE POLICY

Implantable peripheral nerve stimulators and peripheral nerve field stimulators are considered **experimental, investigational, and unproven**. There is insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Peripheral Nerve Stimulators (PNS)

Randomized Controlled Trials

Hatheway et al. (2025) carried out a multicenter randomized controlled trial (COMFORT) to assess whether a micro-implantable pulse generator for peripheral nerve stimulation (PNS) could offer better outcomes than conventional medical management (CMM) alone for people living with chronic peripheral neuropathic pain. Participants were eligible if they had persistent pain in the lower back, knee, shoulder, or foot/ankle stemming from nerve injury, postsurgical or post-traumatic neuralgia, mononeuropathy, or osteoarthritic nerve pain. Individuals with complex regional pain syndrome, neuropathies from metabolic or postherpetic causes, or those taking high-dose opioids (≥90 MME/day) were excluded. The primary outcome was the proportion of patients achieving ≥50% reduction in pain at 3 months, with secondary outcomes focused on pain interference, disability, mood, quality of life, global improvement, and user satisfaction. The active arm achieved an 84% responder rate at 3 months and 88% at 6 months, compared with 3% in the control group ($p<0.001$), along with mean pain reductions of 67% at 3 months and 70% at 6 months, versus 6% in controls ($p<0.001$). Secondary patient-reported outcomes showed significant and consistent improvements in the active arm across all measured domains (typically $p<0.001$), while the control arm showed minimal or no meaningful change. Satisfaction with the device was high, most users found the wearable component comfortable and easy to manage, and no serious device-related complications were reported. Limitations of the study included the control group's limited three-month CMM-only period and the high proportion of female subjects. Overall, the findings indicate that micro-IPG PNS provides clinically meaningful pain relief and functional improvement, offering a safe and effective option for patients whose neuropathic pain has not responded to standard treatments.

Hayek et al. (2025) conducted a prospective, randomized, controlled clinical trial (RCT) to evaluate the effectiveness and safety of a permanent high-frequency electromagnetic coupling (HF-EMC) powered peripheral nerve stimulator (PNS) for chronic craniofacial neuropathic pain. The multicenter study included 60 adults across seven study sites, all implanted with the Freedom Peripheral Nerve Stimulation System (Curonix, LLC). The primary objective was to determine whether active stimulation resulted in greater pain was unresponsive to standard therapies. Eligible

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participants were required to have at least one year of refractory craniofacial neuropathic pain, an average baseline pain score greater than five on a ten-point scale, stable medication regimens, and psychological suitability for implantation. Exclusion criteria included active infection, unresolved malignancy, completed nerve deafferentation, coagulation disorders, or other implanted devices. After a seven-day test period, 93% achieved at least 50% pain reduction. At three months, 69% of participants in the active stimulation group maintained this improvement compared to 11% in the deactivated group (p< 0.001), with mean visual analog scale reductions of 62% and 8.5%, respectively. Following reactivation of the control group, both arms demonstrated comparable, sustained pain and functional improvements through 12 months. No serious adverse events occurred, and minor implant-site discomfort was the most common complaint. Study limitations included the lack of a true placebo group, optional supra- and sub-threshold stimulation settings, and follow-up interruptions due to the COVID-19 pandemic. Overall, this trial provides evidence that permanent high-frequency electromagnetic coupling powered peripheral nerve stimulation is a safe and effective therapy for chronic craniofacial neuropathic pain refractory to conventional treatment.

Schwab et al. (2025) conducted a multicenter, open-label randomized controlled trial (RESTORE) comparing restorative neurostimulation using the ReActiv8 system in adults with chronic mechanical low back pain (CLBP) associated with objectively confirmed multifidus dysfunction. Inclusion criteria required moderate–severe CLBP lasting more than 6 months, failure of conservative and interventional therapies, and at least one positive physical or MRI finding of multifidus dysfunction. Exclusion criteria included prior lumbar spine surgery, radicular or neuropathic pain, and any surgically correctable spinal pathology. The study's primary outcome was change in Oswestry Disability Index (ODI) at 1 year with secondary outcomes including numeric rating scale (NRS) pain scores and health-related quality of life (EQ-5D-5L).Among 203 randomized patients, those receiving restorative neurostimulation demonstrated significantly greater improvement: disability scores improved by an average of 19.7 points compared with 2.9 points in the OMM arm (p < 0.001), pain scores decreased by 3.6 points versus 0.6 points (p < 0.001), and quality-of-life scores increased by 0.155 compared with 0.008 (p < 0.001). Furthermore, 72% of treated patients met composite responder criteria—such as achieving a ≥15-point disability improvement or ≥50% pain reduction—while only 11% of OMM patients met these thresholds (p < 0.001). Device-related adverse events were uncommon and consistent with prior research. Limitations include the unblinded design, potential placebo/nocebo effects, and increased clinical contact for the treatment group. The study's findings demonstrate that restorative neurostimulation is a safe and significantly more effective intervention than standard medical management in adults with chronic mechanical low back pain.

Gilligan et al. (2023, 2021) conducted a RCT to evaluate the safety and efficacy of the PNS system ReActiv8 (Mainstay Medical, Dublin, Ireland) for the treatment of low back pain and subsequently published the two-year follow-up results of said trial. The RCT was an international double-blind sham-controlled trial involving 26 different institutions. Randomization of the total 204 participants was performed after implant surgery to avoid any procedure-related bias, and participants were randomly assigned in a 1:1 ratio to be administered either optimized therapeutic stimulation (102 in the treatment group) or low-level sham stimulation (102 in the control group). Of the 102 in the control group, 101 crossed over into the treatment group after the 120-day intention-to-treat analysis, meaning 176 were included in the one-year analysis. At the 120-day analysis participants who achieved ≥30% low back pain Visual Analog Scale (VAS) improvement without increase in analgesics was not statistically significant between the two groups (57.1% vs 46.6%; difference of 10.4%; 95% CI −3.3% to 24.1%; P = 0.138). Eighteen participants increased analgesics, 9 in each group. In 6 cases, all of which were in the treatment group, the increase in analgesics was unrelated to low back pain. Reasons for increased analgesics in these 6 cases were an ankle fracture, a tooth extraction, an upper respiratory tract infection, an anal abscess, a knee injury, and a renal stone. The mean group difference in VAS improvement (−3.3 vs −2.4; difference of −0.9 cm; 95% CI −1.6 to −0.1 cm; *P* = 0.032) was significant in favor of the treatment, and the cumulative-proportion-of-responders analysis of the primary outcome data showed that across all possible response thresholds, treatment was superior to sham-control (P = 0.0499). Eight device- or procedure-related serious adverse events were reported, all before the 120-day follow-up, six of which were pocket infections. There were no device or procedure related deaths. At the two year follow up VAS scores, Oswestry disability index (ODI) scores, quality-of-life scores, and opioid intake were assessed to reveal that, of the total 156 participants that made it to the 2 year follow up point, the proportion of participants with ≥50% chronic low back pain relief was 71%, and 65% reported chronic low back pain resolution (VAS ≤ 2.5 cm); 61% had a reduction in ODI score of ≥20 points, 76% had improvements of ≥50% in VAS and/or ≥20 points in ODI score, and 56% had these substantial improvements in both VAS and ODI scores. 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.

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Gilligan et al. (2024) published an updated five-year longitudinal analysis of the ReActiv8 trial. This extension study included the original 204 participants and evaluated long-term outcomes using the same core metrics: low back pain intensity (VAS), disability (ODI), and health-related quality of life (EQ-5D-5L). By year five, 126 participants remained in the completer cohort and demonstrated sustained, clinically meaningful benefit. Mean VAS scores improved from 7.3 cm at baseline to 2.4 cm, reflecting a −4.9 cm mean reduction ($p < 0.0001$), with 71.8% achieving ≥50% pain relief and 66.9% meeting the threshold for pain resolution (VAS ≤ 2.5 cm). Disability scores also showed durable improvement, with mean ODI decreasing from 39.1 to 16.5 points ($p < 0.0001$), and 61.1% achieving ≥20-point reductions. Quality-of-life scores improved by 0.231 on the EQ-5D-5L index ($p < 0.0001$), approaching population norms for adults of similar age. Among participants using opioids at baseline, 46% discontinued use and 23% reduced intake by year five. Intent-to-treat mixed-effects modeling confirmed that improvements remained statistically robust despite attrition. Safety findings continued to support the favorable profile reported in earlier publications, with no late device-related serious adverse events and no instances of lead migration. Limitations included expected loss to follow-up over a five-year period and the absence of a long-term control group. Overall, this extended follow-up reinforced that restorative neurostimulation yields durable, clinically substantial improvements in pain, function, and quality of life for a population with historically poor long-term treatment outcomes.

Gilmore et al. (2019) conducted a 60 day double blind placebo controlled RCT with a twelve month follow up to analyze if PNS provides sustained relief from chronic pain. Twenty-eight traumatic lower extremity amputees with residual and/or phantom limb pain were randomized 1:1 to receive 8 weeks of peripheral nerve stimulation of the femoral and sciatic nerves (PNS group) or 4 weeks of sham therapy (placebo group). After the first 4 weeks, PNS group received four additional weeks of stimulation, and the placebo group crossed over to receive active peripheral femoral and sciatic nerve stimulation for 4 weeks. After the completion of the 8-week treatment all leads were removed and both groups were followed monthly for up to 12 months from the initial implantation. The primary outcome was a ≥50% reduction in average daily pain score during weeks 1–4 of the treatment period in all areas of postamputation pain (residual limb pain and/or phantom limb pain) that had baseline average pain scores ≥4. Significantly more participants in the PNS group reported ≥50% reductions in average weekly pain at 12 months (67%, 6/9) compared with the placebo group at the end of the placebo period (0%, 0/14, p=0.001). Similarly, 56% (5/9) of participants in the PNS group reported ≥50% reductions in pain interference at 12 months, compared with 2/13 (15%, p=0.074) in the placebo group at crossover. Reductions in depression were also statistically significantly greater at 12 months in the PNS group compared with the placebo group at crossover.

Systematic Reviews and Meta-Analyses

Machikanti et al. (2025) published a systematic review and meta-analysis of randomized controlled trials evaluating modern peripheral nerve stimulation (PNS) for chronic pain. Randomized controlled trials evaluating implanted or temporary PNS with ≥6-month follow-up for permanent implants or ≥3 months for temporary therapy were included. A total of nine RCTs met the inclusion criteria. Outcome criteria focused on clinically meaningful improvements in pain and function, defined as at least a 50% reduction in pain intensity or a two-point improvement on pain scales, along with measurable gains in physical function and quality of life. PNS was associated with significant reductions in pain intensity and improvements in function and disability compared to control or sham groups at one-month and three-to-twelve-month follow-up intervals. Additional benefits were observed in quality of life and patient-reported outcomes, while adverse events were generally mild, localized, and related to implantation or stimulation procedures, with no serious device-related complications reported. Limitations included small sample sizes, variability in outcome measures, inconsistent comparators, and limited long-term follow-up data, which restricted the generalizability of the findings. The overall evidence supports a fair (Level III) level with moderate certainty and a moderate strength of recommendation for both implantable PNS (following a successful trial or selective lumbar medial branch stimulation without a trial) and temporary 60-day PNS therapy. Additional large-scale, standardized randomized controlled trials with long-term follow-up are needed to confirm the durability of these outcomes and refine patient selection criteria.

Helm et al. (2021) conducted a systematic review on the effectiveness and safety of peripheral nerve stimulation for chronic pain. Between 1966 and June 2021, five RCTs, four observational studies, and four case series met the inclusion criteria of: implanted peripheral nerve stimulators, diagnosis of pain conditions treated by interventional pain physicians, with outcomes measuring pain relief and functional improvement. Of the RCTs evaluating the treatment of peripheral nerve pain, Wilson et al. (2014) found 60% relief at 16 weeks. Deer et al. (2016) using the Bioness StimRouter®, found a mean pain reduction of almost 30% at 12 weeks, compared to a 2.3% reduction in the control group. Gilmore et al. (2020) found that 67% of the treated group had ≥ 50% relief, compared to 0% of the sham group.

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Istek et al. (2014) studied pelvic pain and found that stimulating the tibial nerve for 30 min once a week for 12 weeks provided greater than 50% reduction of pain. The four-case series provide up to 16 years of long-term relief documentation and supported the RCTs with findings of greater than 50% relief in roughly two-thirds of the patients. The authors concluded that there is level II evidence supporting PNS in the treatment of refractory peripheral nerve neuropathic pain due to one high-quality RCT and two moderate-quality RCTs. Four moderate-quality case series reports corroborate the findings of the RCTs and provide documentation of long-term, multiple-year relief. They also emphasized the need for more high quality RCTs to validate the existing evidence, especially since PNS technology is constantly evolving and the mechanisms of therapeutic action are not entirely understood.

Deer at al. (2020) conducted a systematic review to evaluate the efficacy of peripheral nerve stimulation therapies for the treatment of pain. Fourteen RCTs studying electrical stimulation for a variety of painful conditions such as, headache, shoulder pain, back pain, pelvic pain, upper and lower extremity pain, and trunk pain, were included in the systematic literature analysis. Of the RCTs analyzed, six addressed PNS and two addressed PNFS, with the rest studying sphenopalatine ganglion or occipital nerve stimulation. The authors concluded there is strong evidence (Level I) that PNFS is beneficial for patients with continued low back pain following surgery, medications, and/or interventional pain procedures, moderate evidence (Level II) that implanted PNS provides at least modest improvements in mononeuropathic pain and hemiplegic shoulder pain, and fair evidence (Level III) that PNS of the tibial nerve may be helpful for overall pain, dyspareunia, and quality of life in chronic pelvic pain. The authors recommended additional large prospective RCTs to validate the findings and to further determine patient populations and pain diagnoses that would most benefit from this therapy.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

A Health Technology Assessment (Hayes 2025) evaluated the use of percutaneous peripheral nerve stimulation (PNS) with an external pulse generator for adults with chronic pain that has persisted for at least three months despite conservative management. The assessment found that this minimally invasive, nonpharmacological neuromodulation approach—designed to stimulate targeted peripheral nerves and reduce pain signaling—may provide meaningful pain relief, improved function, and reduced reliance on pain medication for some patients. The available studies generally suggest that PNS may provide meaningful reductions in pain intensity, improvements in physical function and quality of life, and decreases in pain medication use, including opioids, for select patients. Reported complications were generally mild and localized—such as skin irritation or discomfort at the device site—with no serious device-related adverse events noted in the reviewed studies. However, the overall evidence quality was rated very low due to the small number of available studies, limited sample sizes, short follow-up durations, and heterogeneity in devices, patient populations, and outcome measures. While preliminary findings are favorable, the evidence remains insufficient to draw definitive conclusions about the long-term efficacy, durability, and comparative value of percutaneous PNS relative to other chronic pain interventions. Hayes emphasizes that additional high-quality, large-scale randomized controlled trials are necessary to confirm its clinical benefits, define optimal patient selection criteria, and assess cost-effectiveness to better inform payer coverage and clinical decision-making.

Gilmore et al. (2023) conducted a prospective, multi-center case series to explore the lasting effects of medial branch PNS on patients with chronic low back pain (CLBP) that had not responded to multiple non-surgical treatments. The study involved 74 adults who underwent a 60-day treatment with an implanted percutaneous PNS device, using it for 6 to 12 hours daily. They were monitored for 14 months (12 months post-treatment) to evaluate changes in pain intensity, disability, pain interference, quality of life, depression, and overall patient impression. Results showed that 91% of participants saw meaningful improvements in at least one outcome after 2 months, which persisted in 79% at 5 months, 73% at 8 months, 75% at 11 months, and 77% at 14 months. Additionally, 77% of participants achieved significant improvements in two or more outcomes at 2 months, 63% at 5 months, 60% at 8 months, 58.9% at 11 months, and 58% at 14 months. Opioid use was notably reduced among 15 of the 20 participants who initially used them, with average morphine equivalent consumption decreasing from 28.5 mg at baseline to 13.4 mg at 2 months and further down to 5.4 mg at 14 months. The study had limitations including the absence of randomization, lack of control over additional treatments, and the varied nature of CLBP diagnoses and prior treatments. Despite these, the authors concluded that 60 days of percutaneous PNS treatment resulted in sustained, clinically meaningful improvements in pain, disability, and pain interference for the majority of participants throughout the 14-month follow-up.

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Peripheral Nerve Field Stimulators (PNFS)

There is limited high quality literature and evidence pertaining to peripheral nerve field stimulation; and of the existing literature, the majority evaluate PNFS as an adjunctive therapy to spinal cord stimulation for chronic back pain. As central nervous system/spinal cord stimulation is not addressed in this policy, this literature has not been included.

Randomized Controlled Trials

Eldabe et al. (2019) conducted a randomized controlled trial of peripheral nerve field stimulation for back pain due to failed back surgery syndrome. A total of 116 participants were randomized: 56 in the PNFS + optimal medical management arm, and 60 in the optimal medical management alone arm. At baseline participants reported low health-related quality of life (EQ-5D-5L UK index: 0.41 ± 0.23; EQ-5D-5L-VAS: 43.6 mm ± 21.2) and severe disability (mean ODI: 49.4 ± 12.7), with neuropathic pain (Douleur Neuropathique 4 score ≥4) in 48.2% of participants. Of the 56 subjects randomized to PNFS + optimal medical management arm, 51 completed the test stimulation procedure, of which 46 (90.2%) had a successful trial and agreed to proceed to permanent implant. The five who declined permanent implant cited no significant pain reduction. The primary outcome was a ≥50% reduction in back pain intensity. At the nine month follow up there was a statistical significance in outcomes between the two arms, 33.9% (n = 19; 95% confidence interval [21.5–46.3%]) met the outcome in the PNFS + optimal medical management arm, compared to 1.7% (n = 1; 95% confidence interval [0.0–4.9%]) in the optimal medical management arm. When removing missing data due to early study termination, the responder rate in the PNFS + optimal medical management arm is 52.8% (95% confidence interval [36.5–69.1%]) compared to 2.8% (95% confidence interval [0.0–8.1%]) in the optimal medical management alone arm. The mean baseline VAS scores were similar in both arms, 68.8 mm (SD = 13.4; n = 56) and 70.2 mm (SD = 14.0; n = 60) in PNFS + optimal medical management and optimal medical management alone arms, respectively. At nine months, the mean back pain score was reduced to 36.9 mm (SD = 24.0; n = 36) in the PNFS + optimal medical management arm, versus in the optimal medical management arm where scores remained stable at 67.5 mm (SD = 18.1; n = 36). Across all 80 implanted subjects, a total of four (5.0%) device or implant related infections occurred, three (3.8%) lead fractures (two noted during the implant procedure and one lead damage postimplant), and two (2.5%) lead dislocation/migrations. There were no cases of lead erosion or participant death. The authors concluded PNFS is a viable treatment option for low back pain, but larger randomized controlled trials are needed to validate these findings.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Ishak et al. (2018) conducted a single center two-year study to evaluate the feasibility, safety, and efficacy of peripheral nerve field stimulation in treatment of low back pain. Twenty-six consecutive patients with chronic low back pain were included in the study. Trial neuromodulation was conducted for 14 days by placing two electrodes were implanted vertically at a depth of 1 cm into the subcutaneous tissue, ≤10 cm from the region of maximum pain. A successful trial was defined as at least 50% pain relief utilizing the VAS. Thirteen patients' trial stimulations were a success and had a permanent neurostimulator implanted. To monitor the effects of permanent neurostimulation, the VAS, ODI, and quality of life were scored preoperatively and at 6-month and 24-month follow-ups. The use of pain medication, including opioid analgesics, was reduced in 92% of patients after 24 months; and the VAS, ODI, and quality of life scores significantly improved in these patients at the 24-month follow-up. The complication rate was 23% (3/13 patients). The authors concluded PNFS is a safe, and effective treatment for chronic low back pain; however, large randomized controlled trials are needed to validate these findings.

National and Specialty Organizations

The **American Society of Pain and Neuroscience (ASPN)** (Gill et al. 2025) developed consensus guidelines outlining evidence-based recommendations for the use of 60-day peripheral nerve stimulation (PNS) therapy in the management of chronic and post-operative pain. These guidelines identify 60-day PNS as an effective, minimally invasive treatment option that provides sustained pain relief without the need for permanent implantation. Evidence demonstrates broad clinical applicability, with the strongest support for phantom and residual limb pain (Grade A; Level I-A) and post-operative knee pain (Grade B; Level I-C). Additional indications include neuropathic pain involving up to two nerves (Grade C; Level I-B), chronic low back pain—including cases following facet radiofrequency ablation or with centralized pain components (Grades B–A; Level I-C)—as well as post-operative foot and ankle pain (Grade C; Level I-A), occipital neuralgia (Moderate; Grade B; Level II), chronic neck pain (Grade C; Level II), and shoulder pain in inoperable or post-surgical cases (Grade B/C; Levels II–I-C). The guidelines emphasize that 60-day PNS preserves normal anatomy, avoids neurodestructive procedures, and can reduce opioid use while achieving durable symptom

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improvement even after device removal. Overall, ASPN concludes that 60-day PNS represents a safe and effective treatment for appropriately selected patients who have failed conservative therapies and may serve as a bridge or alternative to more invasive surgical or permanent neurostimulation options.

The **American Society of Interventional Pain Physicians (ASIPP)** (Manchikanti et al. 2024) guidelines provide an evidence-based framework for the safe and effective use of implantable peripheral nerve stimulation (PNS) in chronic pain management. The effectiveness of both permanent and temporary (used for up to 60 days) implantable PNS system is supported by Level III (fair) evidence with moderate certainty according to GRADE criteria. ASIPP recommends expanding coverage indications to include craniofacial neuropathic pain, phantom limb pain, and both nociceptive and neuropathic low back pain, as these conditions have shown meaningful clinical improvement with PNS therapy. The guidelines emphasize that PNS should be reserved for patients with chronic pain unresponsive to at least two conservative treatments, following appropriate diagnostic evaluation, psychological screening, and patient education regarding expectations and post-implant management. ASIPP further underscores the importance of understanding each device's technical characteristics to ensure proper selection and implantation, and identifies patient education as a key factor influencing treatment success. Modern PNS technologies—such as the Freedom® (Curonix), StimRouter® (Bioventus), SPRINT® (SPR Therapeutics), Nalu™ (Nalu Medical), and ReActiv8® (Mainstay Medical) systems—represent a significant advancement from historical open neurosurgical procedures to minimally invasive, FDA-cleared options for chronic pain management. Overall, ASIPP concludes that PNS is a safe, effective, and evidence-supported option for appropriately selected patients when performed within established procedural, safety, and risk management standards.

The **American Society of Pain and Neuroscience (APSN)** (Strand et al. 2022) published evidence-based best practice guidelines for the use of implantable peripheral nerve stimulation (PNS) for chronic pain. For conditions involving the upper extremities, PNS may provide modest, short-term pain relief, improved physical function, and enhanced qualities of life for individuals with chronic hemiplegic shoulder pain (Level of Evidence [LoE] II-3, Grade B). In cases of mononeuropathies affecting the upper extremity, PNS may be offered after a positive diagnostic ultrasound-guided nerve block of the targeted nerve and has been shown to result in modest to moderate pain relief (LoE II-2, Grade B). Regarding the low back and trunk, subcutaneous peripheral field stimulation combined with optimal medication management may produce moderate improvement in pain intensity among patients with failed back surgery compared to medication management alone (LoE I, Grade B). Evidence also supports that stimulation of the lumbar medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial or mechanical low back pain (LoE II-2, Grade B). There is limited evidence suggesting that PNS may reduce pain in neuropathic syndromes of the trunk and back, including radiculopathy and post-herpetic neuralgia (LoE III, Grade C). For the lower extremities, PNS may be considered for neuropathic pain after conservative therapies have failed, offering modest pain relief (LoE I, Grade B). Similarly, for post-amputation pain in the lower extremity, PNS may be considered following unsuccessful conservative treatment and is associated with modest to moderate pain reduction (LoE I, Grade B). In other considerations, PNS represents a less invasive alternative to spinal cord stimulation (SCS) and may be an option for patients with Complex Regional Pain Syndrome (CRPS) Types I and II. Although PNS may provide modest improvements in pain intensity and functional outcomes in CRPS, the current evidence remains limited, and other neuromodulation interventions, such as dorsal root ganglion spinal cord stimulation, are generally preferred (LoE III, Grade C). PNS procedures carry a low-to-intermediate risk of bleeding complications, which varies depending on the location of the targeted nerve, proximity to critical vessels, and the invasiveness of implantation.

The **International Neuromodulation Society** (Deer et al. 2017) published a Neuromodulation Appropriateness Consensus safety guideline outlining best practices for the safe application of peripheral nerve stimulation (PNS). The guideline indicates that PNS has not been associated with direct neurological injury and is considered a low-risk procedure (LoE II-3, Grade B). It further recommends the use of imaging guidance and intermittent nerve stimulation during percutaneous PNS placement to enhance procedural accuracy and safety (LoE II, Grade I). Additionally, the use of specialized equipment designed specifically for PNS is encouraged, as it is expected to improve therapeutic efficacy, enhance safety, and reduce complication rates (LoE III, Grade B).

The **National Institute for Health and Care Excellence (NICE)** has issued multiple guidance documents addressing the use of neurostimulation and peripheral nerve field stimulation for chronic low back pain. In its 2022 guidance on interventional procedures involving neurostimulation of the lumbar muscles for refractory, non-specific chronic low back pain, NICE determined that the available evidence on both the safety and effectiveness of this approach remains

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limited and inconclusive. As a result, NICE recommends that neurostimulation for lumbar muscle pain should only be performed under strict clinical governance frameworks, with comprehensive patient consent, ongoing monitoring, or within the context of formal research studies (NICE 2022) .

In 2013, NICE released an interventional procedures guidance on peripheral nerve field stimulation for chronic low back pain. This evidence-based assessment concluded that implanting subcutaneous electrodes connected to a neurostimulator to alter pain signal transmission lacks sufficient high-quality evidence to establish safety and efficacy. Due to the limited quality and quantity of existing research, NICE advises that peripheral nerve field stimulation should be reserved for exceptional clinical cases and only undertaken after discussion and agreement within a multidisciplinary care team (NICE 2013).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
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
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, 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	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, 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 simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, 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 complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
64999	Unlisted procedure, nervous system [when specified as Peripheral Nerve Field Stimulation]

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HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
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
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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
12/11/2024	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
02/14/2024	Coding and billing updated.
12/13/2023	New policy. IRO Peer Review in December 2023 by a practicing physician board-certified in Pain Management.

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